SOLICITATION

SECTION A - SOLICITATION/CONTRACT FORM

1. Requisition or other Purchase Authority: _____		
2. **Request for Proposal (RFP) Number:** N01CN05014-69	3. **Issue Date:** March 25, 2011	4. **Set Aside:** [X] No [ ] Yes See Part IV Section L
5. Title : Cancer Prevention Agent Development Program: Early Phase Clinical Research		
6. ISSUED BY: NCI, Office of Acquisitions National Institutes of Health		7. SUBMIT OFFERS TO: See Part III, Section J, "Packaging and Delivery of the Proposal," ATTACHMENT 1 of this Solicitation.
8. Proposals for furnishing the supplies and/or services in THE SCHEDULE will be received at the place specified in, and in the number of copies specified in Attachment 1, "Packaging and Delivery of the Proposal," until 3:00 PM local time on July 25, 2011. Offers will be valid for 120 days unless a different period is specified by the offeror on the Attachment entitled, "Proposal Summary and Data Record, NIH 2043.		
9. This solicitation requires delivery of proposals as stated in ATTACHMENT 1, "PACKAGING AND DELIVERY OF THE PROPOSAL." If proposals are requred to be delivered to two different locations, the OFFICIAL POINT OF RECEIPT for determining TIMELY DELIVERY is the address provided for the OFFICE OF ACQUISITIONS. IF YOUR PROPOSAL IS NOT RECEIVED BY THE CONTRACTING OFFICER OR HIS DESIGNEE AT THE PLACE AND TIME SPECIFIED FOR THE OFFICE OF ACQUISITIONS, THEN IT WILL BE CONSIDERED LATE AND HANDLED IN ACCORDANCE WITH subparagraph (c)(3) of FAR Clause 52.215-1, Instructions to Offerors--Competitive Acquisition," LOCATED IN SECTION L.1. OF THIS SOLICITATION.		
10. Offeror must be registered in the Central Contractor Registry (CCR) prior to award of a contract. http://www.ccr.gov		
11. FOR INFORMATION CALL: Donna Perry-Lalley PHONE: 301-435-3776 e-MAIL: perryd@mail.nih.gov COLLECT CALLS WILL NOT BE ACCEPTED.		
A Pre-Proposal Conference/teleconference will be held in Bethesda, MD on April 27, 2011 from 11am -2pm. See details in Section L, item 1.d. Also, note the additional instructions in Section L: Additional Technical Proposal Instructions and Additonal Business Proposal Instructions in preparing proposals.		Virginia DeSeau Contracting Officer Office of Acquisitions

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PART I - THE SCHEDULE

THE INFORMATION SET FORTH IN **SECTION A - SOLICITATION/CONTRACT FORM**, HEREIN CONTAINS IMPORTANT INFORMATION FOR ANY OFFEROR INTERESTED IN RESPONDING TO THIS SOLICITATION. ANY CONTRACT RESULTING FROM THIS SOLICITATION WILL INCLUDE IN ITS **SECTION A - SOLICITATION/ CONTRACT FORM**, ACCOUNTING, APPROPRIATION AND GENERAL INFORMATION APPLICABLE TO THE CONTRACT AWARD.

THE CONTRACT SCHEDULE SET FORTH IN **SECTIONS B THROUGH H**, HEREIN, CONTAINS CONTRACTUAL INFORMATION PERTINENT TO THIS SOLICITATION. IT IS NOT AN EXACT REPRESENTATION OF THE CONTRACT DOCUMENT THAT WILL BE AWARDED AS A RESULT OF THIS SOLICITATION. THE CONTRACT COST OR PRICE AND OTHER CONTRACTUAL PROVISIONS PERTINENT TO THE OFFEROR (i.e., those relating to the organizational structure [e.g., Non-Profit, Commercial] and specific cost authorizations unique to the Offeror's proposal and requiring Contracting Officer Prior Approval) WILL BE DISCUSSED IN THE NEGOTIATION PROCESS AND WILL BE INCLUDED IN THE RESULTANT CONTRACT. THE ENCLOSED CONTRACT SCHEDULE IS INTENDED TO PROVIDE THE OFFEROR WITH THE NECESSARY INFORMATION TO UNDERSTAND THE TERMS AND CONDITIONS OF THE RESULTANT CONTRACT.

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The Contractor shall provide essential clinical trials infrastructure and laboratory support to assess the cancer preventive potential of various agents. The goals of the program are:

1. To efficiently design and conduct early phase clinical trials to assess various classes of potential cancer preventive agents.
2. To characterize the biological effects of new cancer preventive agents on their defined molecular targets as well as on multiple endpoints associated with carcinogenesis, such as proliferation, apoptosis, growth factor expression, oncogene expression, and others.
3. To correlate the biological effects with clinically relevant endpoints.
4. To develop scientific insights into the mechanisms of cancer prevention by the agents examined and to continue to develop novel potential markers as determinants of response.

ARTICLE B.2. ESTIMATED COST - OPTION

a. The estimated cost of the Base Period of this contract is $_____.

b. If the Government exercises its option pursuant to the OPTION PROVISION Article in SECTION H of this contract, the Government's total estimated contract amount represented by the sum of the estimated cost plus the fixed fee will be increased as follows:

	Estimated Cost ($)
Base Period:	
Option Periods: Option 1 Option 2	
Option Quantities: Subjects Option 1: 12 subjects Option 2: 12 subjects Option 3: 13 subjects	

	Estimated Cost ($)
Option 4: 13 subjects	
Total [Base Period and Option(s)]	

ARTICLE B.3. ESTIMATED COST - INCREMENTALLY FUNDED CONTRACT, HHSAR 352.232-71 (June 2010)

a. The total estimated cost to the Government for full performance of this contract, including all allowable direct and indirect costs, is $_____.

b. The following represents the schedule* by which the Government expects to allot severable funds to this contract:

CLIN, Task, Number, or Description	Start Date of Period or Increment of Performance	End Date of Period or Increment of Performance	Estimated Cost ($)
TBD			
			[Total]

*To be inserted after negotiation

c. Total funds currently obligated and available for payment under this contract are $_____ .

d. The Contracting Officer may issue unilateral modifications to obligate additional funds to the contract and make related changes to paragraphs b. and/or c., above.

e. Until this contract is fully funded, the requirements of the clause at FAR 52.232-22, Limitation of Funds, shall govern. Once the contract is fully funded, the requirements of the clause at FAR 52.232-20, Limitation of Cost, shall govern.

(End of Clause)

ARTICLE B.4. PROVISIONS APPLICABLE TO DIRECT COSTS

This article will prohibit or restrict the use of contract funds, unless otherwise approved by the Contracting Officer. The following is a list of items that may be included in the resultant contract as applicable. 1) Acquisition, by purchase or lease, of any interest in real property; 2) Special rearrangement or alteration of facilities; 3) Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value; 4) Travel Costs; 5) Consultant Costs; 6) Subcontract Costs; 7) Patient Care Costs; 8) Accountable Government Property; and 9) Research Funding.

ARTICLE B.5. ADVANCE UNDERSTANDINGS

Specific elements of cost, which normally require prior written approval of the Contracting Officer before incurrence of the cost (e.g., foreign travel, consultant fees, subcontracts) will be included in this Article if the Contracting Officer has granted his/her approval prior to contract award.

a. **Complexity Model Table 1**

The following table sets forth the rates for the Per Subject Costs for the first year that budgets for protocols are approved, tentatively 2013. Each subsequent year from 2014 - 2017, a revised table will be calculated factoring in an escalation factor of 2% to be applied to the rates.

Stage	Base Cost	x 1.5	x 2.0	x 2.5	x 3.0
Screening 1	$ x	$ 1.5x	$ 2x	$ 2.5x	$ 3x
Screening 2	$ y	$ 1.5y	$ 2y	$ 2.5y	$ 3y
Intervention	$ z	$ 1.5z	$ 2z	$ 2.5z	$ 3z

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

a. Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work, dated March 16, 2011, attached hereto and made a part of this Solicitation (See SECTION J - List of Attachments).

b. The applicable Privacy Act System of Records Number will be specified and shall be used in any design, development, or operation work to be performed under the resultant contract. Disposition of records shall be in accordance with SECTION C of the contract, and by direction of the Contracting Officer's Technical Representative (COTR).

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format. In addition, one hardcopy of each report shall be submitted to the Contracting Officer.

All reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including specific checklists, by application, can be found at: http://www.hhs.gov/web/508/index.html under "Helpful Resources."

a. **Technical Progress Reports**

1. In addition to the required reports set forth elsewhere in this Schedule, the preparation and submission of regularly recurring Technical Progress Reports will be required in any contract resulting from this solicitation. These reports will require descriptive information about the activities undertaken during the reporting period and will require information about planned activities for future reporting periods. The frequency and specific content of these reports will be determined prior to contract award. *[Note: Beginning May 25, 2008, the Contractor shall include the applicable PubMed Central*

or NIH Manuscript Submission reference number when citing publications that arise from its NIH funded research.]

For proposal preparation purposes only, it is estimated that in addition to the required electronic versions 1 hard copy of these reports will be required as follows:

[X] Monthly Data Reporting - Protocol Specific
[X] Quarterly
[ ] Semi-Annually
[X] Annually
[ ] Annually (with a requirement for a Draft Annual Report)
[ ] Final - Upon final completion of the contract
[X] Final - Upon final completion of the contract (with a requirement for a Draft Final Report)

1.1 Monthly Data Reporting - Protocol Specific

The Contractor shall report individual protocol-specific information including, but not limited to, participant accrual and characteristics, agent dosing, adverse events, and endpoint, response, and/or outcome data.

The Contractor shall provide all data to the Division of Cancer Prevention (DCP) electronically using DCP's secure file transfer site. This submission method requires the Contractor to develop and/or implement computer programs to download data from the Contractor's current clinical trials management system/clinical data management system to DCP's secure file transfer site. All data elements used in the collection of data for DCP-sponsored clinical trial must be Common Date Element (CDE)-compliant. (Note: These data elements may change as Government requirements evolve.) Acceptable file transfer formats include: MS Excel (saved as CSV file), XML, and Text delimited flat file.

DCP will evaluate the submitted data files for completeness and accuracy. The Contractor will be notified of any problems with a data submission. The Contractor shall be required to make corrections and resubmit the entire data set within 2 weeks following receipt of DCP comments.

Select clinical trials may require the reporting of data in addition to that required for the routine Monthly Data Reporting. Those specific additional data elements will be determined and defined during the development of the trial and as needed during the conduct of the trial to address changing scientific and safety concerns.

The monthly data submissions are due by the 10th calendar day of each month and should reflect the status of data as of the end of the preceding month. The first submission is due the month after the protocol has received Final Study Approval. These submissions are required for all approved studies until they reach a status of 'complete' or 'administratively complete'.

1.2. Quarterly and Annual Progress Reports

The purpose of the Quarterly and Annual Progress Reports is to provide a description of the activities during the reporting period, the adverse events table, a discussion of any problems encountered, and to detail the activities planned for the ensuing reporting period. The Quarterly and Annual Progress Reports summarize the progress of the contract and provide specific information on each individual clinical trial including expenditure summaries. The format for these progress reports shall be specified by DCP.

All Quarterly and Annual Progress Reports shall be submitted electronically to the Contracting Officer (CO) and Contracting Officer's Technical Representative (COTR). In addition, reports will be submitted electronically to the Protocol Information Office at: nci_dcp_pio@mail.nih.gov. The first reporting period consists of the first full three calendar months of performance plus any fraction of the initial month. Thereafter, the Quarterly Progress Report shall be due 30 calendar days following each

quarter. At the end of each contract year an Annual (cumulative) Progress Report shall be submitted within 42 calendar days following the end of each contract year in lieu of the Quarterly Progress Report.

If applicable, the Government will act as Sponsor of the Investigational New Drug (IND) under the Code of Federal Regulations §312. The Code specifies that the Investigator shall furnish reports to the Sponsor who is required under §312.33 to submit annual reports to FDA on the progress of the clinical investigations. It is noted for informational purposes that CFR 312.60 requires the Principal Investigator, who has committed by signing Form FDA 1572, to personally conduct or supervise the described investigations under applicable regulations, to report the conduct and progress of the clinical investigation to the authorized representative(s) of the Government and the Sponsor of the clinical investigation, in this case the National Cancer Institute, Division of Cancer Prevention.

1.3. Human Subject Education Certification

The Principal Investigator and all Key Personnel shall submit documentation of the required education to DCP's Regulatory Contractor within sixty (60) calendar days of contract award. Prior to the substitution of the principal investigator or any other individuals responsible for the design and conduct of the research under contract, the contractor shall provide the following written information to the Contracting Officer: the title of the education program and a one sentence description of the program that has been completed by the replacement.

1.4. Draft Final and Final Contract Report

The Final Report summarizes work performed and results obtained for the entire contract period of performance. The report shall be prepared according to the document "NCI Requirements for Final Reports for Clinical Trials" as found at: http://dcp.cancer.gov/Files/clinical-trials/final-report.pdf. A Draft of the Final Report, including all calculated and raw data, shall be submitted to the Division of Cancer Prevention for review by the COTR. This Draft is due at least 60 calendar days before the end of the contract. The DCP COTR will review and respond with approval or comments to the draft Final Report within 30 calendar days of submission. The Final report is due by the date of contract expiration. An Annual Report will not be required for the period when the final report is due.

The Draft Final Report and the Final Report shall be submitted electronically to the Protocol Information Office to: nci_dcp_pio@mail.nih.gov, the COTR, and the CO. The Contractor shall also provide a disc of the Final Report to the COTR and the CO.

2. **Summary of Salient Results**

The Contractor will be required to prepare and submit, with the final report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract. This report will be required on or before the expiration date of the contract.

3. **Annual Technical Progress Report for Clinical Research Study Populations**

The Contractor shall submit information about the inclusion of women and members of minority groups and their subpopulations for each study being performed under this contract. The Contractor shall submit this information in the format indicated in the attachment entitled, "Inclusion Enrollment Report," which is set forth in SECTION J of this contract. The Contractor also shall use this format, modified to indicate that it is a final report, for reporting purposes in the final report.

The Contractor shall submit the report in accordance with the DELIVERIES Article in SECTION F of this contract.

In addition, the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended, October, 2001 applies. If this contract is for Phase III clinical trials, see II.B of these guidelines. The Guidelines may be found at the following website:

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm

Include a description of the plans to conduct analyses, as appropriate, by sex/gender and/or racial/ethnic groups in the clinical trial protocol as approved by the IRB, and provide a description of the progress in the conduct of these analyses, as appropriate, in the annual progress report and the final report. If the analysis reveals no subset differences, a brief statement to that effect, indicating the subsets analyzed, will suffice. The Government strongly encourages inclusion of the results of subset analysis in all publication submissions. In the final report, the Contractor shall include all final analyses of the data on sex/gender and race/ethnicity.

b. **Other Reports/Deliverables**

1. **Information Security and Physical Access Reporting Requirements**

The Contractor shall submit the following reports as required by the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract. Note: Each report listed below includes a reference to the appropriate subparagraph of this article.

a. **Roster of Employees Requiring Suitability Investigations**

The Contractor shall submit a roster, by name, position, e-mail address, phone number and responsibility, of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access, or host and/or maintain a Federal information system(s). The roster shall be submitted to the Contracting Officer's Technical Representative (COTR), with a copy to the Contracting Officer, within 14 calendar days of the effective date of the contract. (Reference subparagraph A.e. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

b. **Reporting of New and Departing Employees**

The Contractor shall notify the Contracting Officer's Technical Representative (COTR) and Contracting Officer within five working days of staffing changes for positions that require suitability determinations as follows:

a. **New Employees who have or will have access to HHS Information systems or data:** Provide the name, position title, e-mail address, and phone number of the new employee. Provide the name, position title and suitability level held by the former incumbent. If the employee is filling a new position, provide a description of the position and the Government will determine the appropriate security level.

b. **Departing Employees:** 1) Provide the name, position title, and security clearance level held by or pending for the individual; and 2) Perform and document the actions identified in the "Employee Separation Checklist", attached in Section J, ATTACHMENTS of this contract, when a Contractor/Subcontractor employee terminates work under this contract. All documentation shall be made available to the COTR and/or Contracting Officer upon request.

(Reference subparagraph E.2.a-c. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

c. **Contractor - Employee Non-Disclosure Agreement(s)**

The contractor shall complete and submit a signed and witnessed "Commitment to Protect Non-Public Information - Contractor Agreement" form for each contractor

and subcontractor employee who may have access to non-public Department information under this contract. This form is located at: http://ocio.nih.gov/docs/public/Nondisclosure.pdf.

(Reference subparagraph E.2.d. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

2. **Section 508 Annual Report**

The contractor shall submit an annual Section 508 report in accordance with the schedule set forth in the ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY Article in SECTION H of this contract. The Section 508 Report Template and Instructions for completing the report are available at: http://www.hhs.gov/od under "Vendor Information and Documents."

3. **Deliverables Required Prior to Initiating Any Clinical Trial**

a. Multi-Institution Monitoring Plan
The Multi-Institution Monitoring Plan is due within 30 calendar days of the contract effective date. The Contractor shall submit a Plan describing implementation of appropriate procedures to ensure compliance with the DCP Multicenter Guidelines (see http://prevention.cancer.gov/clinicaltrials/management/consortia/step-1/multi). The Plan shall be sent to the PIO for distribution to the COTR. The Multi-Institution Monitoring Plan shall be approved by the COTR prior to initiation of any clinical trial.

b. Master Data and Safety Monitoring Plan
A Master Data and Safety Monitoring Plan (DSMP), reflecting procedures to be implemented across all studies within the Contractor's network, is due within 60 calendar days of the contract effective date. It shall be approved by DCP before it can become effective. Additionally, a protocol-specific DSMP is required with the submission of each protocol and must be approved by the DCP before the clinical trial may commence. The protocol-specific DSMP should reference the approved Master DSMP and only needs to contain information that customizes the DSMP to a specific protocol or differences from the Master DSMP. The NIH policy reference, purpose, essential elements and other requirements for this Plan can be found at http://prevention.cancer.gov/clinicaltrials/management/consortia/step-3/guide; http://www.cancer.gov/clinicaltrials/conducting/dsm-guidelines.

4. **Deliverables Required Prior to Initiation of Each Clinical Trial**

a. Letters of Intent (LOIs)
The Letter of Intent (LOI) is a document prepared and submitted by the Principal Investigator to declare interest in conducting a particular clinical trial. The LOI process is further defined in the Statement of Work (SOW, Section 2.a, "The Letter of Intent Process"). The LOI Guidelines and Form are available at: http://prevention.cancer.gov/clinicaltrials/management/consortia/step-1/protocol#loi

b. Contract Work Assignment
The Contract Work Assignment will be completed and submitted with the Protocol Document in accordance with Article G in the contract.

c. Protocol Document
LOIs approved by the DCP LOI Review Committee shall be developed into complete protocol documents by the Principal Investigator. The protocol document with informed consent document, and all Additional Study Related Documents are due to DCP within 60 calendar days of the Principal

Investigator's notification of LOI approval. The protocol shall include the essential elements and follow the template on the DCP web site http://prevention.cancer.gov/clinicaltrials/management/consortia/step-1/protocol. The Protocol Document shall also include the budget based on the number of subjects to be accrued, protocol-specific costs, and proposed biomarker analyses (see d. below). The protocol shall incorporate required changes from the LOI review committee. The protocol and attachments shall be submitted to the DCP PIO as an electronic attachment (MS Word). Any further revisions requested by DCP shall be submitted as a revised protocol according to the format and time lines specified by the PIO.

d. Biomarker and Pharmacokinetic Method Development Document

All pharmacokinetic and biomarker laboratory techniques, assays, and procedures shall be validated according to the parameters described in the URL under the Protocol Document above (see section in URL entitled "Protocol Process"; document entitled "Additional Study Related Documents") and a report prepared for Division of Cancer Prevention approval within 60 calendar days of approval of an LOI (as part of the Additional Study Related Documents submitted with the protocol).
A budget for the techniques, assays, and procedures to be used for each specific protocol shall be submitted with the LOI. Each technique, assay, and procedure shall be budgeted on a per specimen, per test basis and shall be separately negotiated per protocol.

e. Protocol-related administrative and regulatory documents

DCP or its contractors will notify the investigator of the specific regulatory and administrative documents required for FDA submission and/or protocol initiation. Documents include, but are not limited to:
i) Principal Investigator Form FDA 1572, biosketch and sub-investigator biosketches
ii) Any additional documentation required by a pharmaceutical partner
iii) IRB approval of protocol, consent, promotional materials, data and safety monitoring plan
iv) IRB committee membership roster
v) Lab certifications (CLIA, CAP)
vi) List of lab normal ranges
vii) Delegation of authority form, as appropriate
viii) Human Subjects Education verification

5. **Deliverables Required During the Conduct of Each Clinical Trial**

a. Participants Data
Clinical trial data for each participant using paper based or electronic reporting as specified by DCP will be required. Reportable data shall include, but may not be limited to: administrative data elements, treatment administration details, adverse events, response data, demographic data.

b. Adverse Event Reports
All serious adverse events (SAEs), whether judged to be drug related or not, must be reported to the DCP Medical Monitor according to the guidelines below. Adverse events shall be graded according to the Common Terminology Criteria for Adverse Events (CTCAE). Studies will be conducted under the latest version of the CTCAE or as required by DCP. A complete set of the CTCAE and instructions for use are available at: http://ctep.cancer.gov/protocolDevelopment/electronic_applications/ctc.htm
In addition to reporting these events on the Case Report Form a cumulative table describing all adverse events is required in the Quarterly, Annual, and Final reports.

Adverse Event Reporting Chart:
Summary of Investigator's Obligations for Reporting Adverse Events in Phase 0-II Clinical Trials to the National Cancer Institute, Division of Cancer Prevention (DCP)

Reaction	*Reporting Obligation*
a. ALL SERIOUS ADVERSE EVENTS (Fatal, all life-threatening events, any adverse event drug experience occurring at any dose that results in the following: inpatient hospitalization or prolongation of existing hospitalization, persistent or significant disability/incapacity, or is a congenital anomaly/birth defect.	Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse event when, based upon appropriate medical judgement, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.
b. ALL ADVERSE EVENTS (SERIOUS, NON-SERIOUS) [3]	REPORT BY PHONE TO DCP WITHIN 24 HOURS. [1] (written report to follow within 48 hrs [2]) REPORT in the Adverse Event Case Report Form and Quarterly/Annual Progress Reports.

1. Report to Medical Monitor for the specific trial
2. Use Common Terminology Criteria for Adverse Events (CTCAE), most recent version.
3. A list of all known toxicities can be found in the Investigator's Brochure of package insert of agent. An Investigator shall promptly report to the Sponsor (National Cancer Institute, Division of Cancer Prevention, Medical Monitor) any adverse effect that may reasonably be regarded as caused by, or probably caused by the drug. If the non-serious adverse event is alarming, the Investigator shall report the adverse effect immediately.

c. Protocol Amendments
Administrative and Scientific amendments must be submitted to DCP PIO for review and approval by the COTR and the Medical/Scientific Monitor.

6. **Deliverables Required Following Completion of Each Clinical Trial**

a. Draft and Final Study Manuscript: A 'draft' or 'submission' manuscript shall be submitted within 120 calendar days of the time that all participants have met the primary study endpoint. All submitted manuscripts shall be clearly labeled on the cover page as either draft or submission version. Final Study Manuscripts shall be provided to DCP PIO and the NIH Library of Medicine one month after publication.

b. Data set for analysis: final clinical and safety data should be submitted to DCP's regulatory contractor within 120 calendar days of the last patient's exit from the clinical protocol; biomarker data may follow. The data provided should be a copy of the final, complete, cleaned, audited, locked data set used for analysis.

c. Biomarker and Other Laboratory Study Analyses: The results of secondary biomarker analyses may not be available until after the primary manuscript is written. The due date of the report regarding biomarker analyses not included in the primary study manuscript will be negotiated with the Medical/ Scientific Monitor.

d. Biologic Specimens: Biologic specimens collected during the conduct of each clinical trial that are not used during the course of the study will be considered deliverables under the contract and thus be the property of the NCI. At study completion, NCI reserves the option to either retain or relinquish ownership of the unused biologic specimens. If NCI retains ownership of specimens, the Contractor shall collect, verify, and transfer the requested biologic specimens from the site to an NCI-specified repository or laboratory at NCI's expense.

SECTION D - PACKAGING, MARKING AND SHIPPING

All deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications. At a minimum, all deliverables shall be marked with the contract number and Contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

SECTION E - INSPECTION AND ACCEPTANCE

a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.

b. For the purpose of this SECTION, the Contracting Officer's Technical Representative is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed at:
National Cancer Institute
Bethesda, Maryland

Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.

FAR Clause **52.246-8, Inspection of Research and Development - Cost-Reimbursement** (May 2001).

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

a. The period of performance of this contract shall be from June 16, 2012 through June 15, 2017.

b. If the Government exercises its option(s) pursuant to the OPTION PROVISION Article in Section H of this contract, the period of performance will be increased as listed below:

Option	Option Period
1	
2	

ARTICLE F.2. DELIVERIES

Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in the Statement of Work Article in SECTION C of this contract and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule:

a. The items specified below as described in the REPORTING REQUIREMENTS Article in SECTION C of this contract will be required to be delivered F.o.b. Destination as set forth in FAR 52.247-35, F.o.b. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the date(s) specified below [and any specifications stated in SECTION D, PACKAGING, MARKING AND SHIPPING, of this contract]:

Item No.	Deliverable Description	Addressee	Due Date
1	Multi-Institution Monitoring Plan	PIO, COTR	30 calendar days after contract award
2	Master Data and Safety Monitoring Plan	PIO, COTR	60 calendar days after contract award
3	Protocol-specific Data and Safety Monitoring Plan	PIO	To be provided with the submission of each protocol
4	Human Subjects Education certification	DCP's regulatory contractor	Within 60 calendar days of award and yearly thereafter
5	Letter of Intent (LOI)	PIO	60 calendar days after DCP announcement of the request for LOIs
6	Contract Work Assignment	COTR	With submission of Protocol
7	Protocol with informed consent document, appendices, and all Additional Study Documents	PIO	First submission due 60 calendar days from DCP approval of LOI, and Revisions due as specified in the Consensus Review document
8	Protocol Amendments	PIO	As necessity determines after protocol is initiated
9	Biomarker and Pharmacokinetic Method Development Document	PIO	First submission due 60 calendar days from DCP approval of LOI, and Revisions due as specified in the Consensus Review document
10	Monthly Data Reporting- Protocol Specific	DCP's secure file transfer site	10th calendar day of the month after Final Study Approval
11	Protocol-related administrative and regulatory documents	DCP's regulatory contractor	Prior to Final Study Approval, in consultation with COTR
12	Adverse Events Reports	Study Medical Monitor	Due in accordance with DCP Adverse Event Reporting Chart
13	Biological specimens	DCP's specimen biorepository (site to be determined)	Prior to or upon expiration of contract, as requested by COTR
14	Draft and Final Study Manuscript	PIO, Study Medical/ Scientific Monitor	Draft: 120 calendar days after completion of study Final: one month after publication
15	Biomarker and Other Laboratory Study Analyses	PIO, Study Medical/ Scientific Monitor	After completion of study and as agreed upon with study Medical/Scientific Monitor
16	Complete, cleaned, audited, locked data set (on disc)	DCP's regulatory contractor (to be determined)	120 calendar days after completion of study
17	Quarterly Progress Reports including expenditure summary for each clinical trial	PIO, COTR, CO	30 calendar days following the end of each quarter
18	Annual Progress Report	PIO, COTR, CO	42 calendar days following the end of each contract year
19	Inclusion Enrollment Report	PIO, COTR, CO	Annually
20	Draft Final Contract Report	PIO, COTR, CO	60 calendar days prior to the expiration date of the contract
21	Final Contract Report	PIO, COTR, CO	By Contract expiration date
22	Roster of Employees Requiring Suitability Investigations	COTR, CO	Fourteen (14) calendar days after award

Item No.	Deliverable Description	Addressee	Due Date
23	Reporting of New and Departing Employees	COTR, CO	Within five working days of staffing changes for positions that require suitability determinations
24	Contractor - Employee Non-Disclosure Agreement(s)	COTR, CO	Prior to commencing work on the contract
25	Section 508 Report	COTR, CO	Sixty (60) calendar days prior to the end of each contract year.

b. The above items shall be addressed and delivered to:

Addressee
Contracting Officer's Technical Representative (COTR) Division of Cancer Prevention National Cancer Institute Executive Plaza North, Room 6130 EXECUTIVE BLVD BETHESDA, MD 20892
DCP Protocol Information Office (PIO) Division of Cancer Prevention National Cancer Institute Executive Plaza North, Room 2050 6130 EXECUTIVE BLVD BETHESDA, MD 20892 **Preferred electronic delivery to: nci_dcp_pio@mail.nih.gov**
Contracting Officer (CO) Research Contracts and Acquisition Branch National Cancer Institute Executive Plaza South, Room 603 6120 EXECUTIVE BLVD MSC 7220 BETHESDA, MD 20892-7220
DCP's Regulatory Contractor - Will be provided
Study Medical/Scientific Monitor - Will be provided

ARTICLE F.3. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)

This contract incorporates the following clause(s) by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. Also, the full text of a clause may be accessed electronically at this address: http://www.acquisition.gov/comp/far/index.html

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (August 1989) with **Alternate I** (April 1984).

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. CONTRACTING OFFICER'S TECHNICAL REPRESENTATIVE (COTR)

The following Contracting Officer's Technical Representative (COTR) will represent the Government for the purpose of this contract:

To be specified prior to award

The COTR is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The alternate COTR is responsible for carrying out the duties of the COTR only in the event that the COTR can no longer perform his/her duties as assigned.

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

The Government may unilaterally change its COTR designation.

ARTICLE G.2. KEY PERSONNEL, HHSAR 352.242-70 (January 2006)

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. The Government may modify the contract to add or delete key personnel at the request of the Contractor or Government.

(End of Clause)

The following individual(s) is/are considered to be essential to the work being performed hereunder:

Name	Title

When Multiple Principal Investigators are named, the "Contact PI" MUST be specified

ARTICLE G.3. WORK ASSIGNMENT PROCEDURES

In providing support under this contract, the Contractor shall initiate work only when so directed by a Work Assignment (Attachment provided in SECTION J). Approval of a Work Assignment shall **not** constitute approval to exceed any item listed in the contract or general clauses of the contract. Work Assignment amounts shall not exceed the total amounts listed in the contract (time, dollars, effort, consultants, travel, etc.). The Contracting Officer's Technical Representative (COTR) with Contracting Officer approval, is authorized to initiate Work Assignments and to sign Work Assignments indicating satisfactory performance/delivery of the services/product required in each Work Assignment. The Contractor shall assure, prior to commencing work on any Work Assignment, that written approval of the COTR and the Contracting Officer has been obtained. A Work Assignment which does not contain both Contracting Officer and COTR approval signatures shall be considered invalid and costs incurred for such work shall be considered unallowable. The Contractor shall not exceed the estimated labor hours, estimated Work

Assignment amount, or change the Work Assignment leader without prior written approval of the COTR and the Contracting Officer by modification of the Work Assignment. The day-to-day operational and administrative details of the Work Assignment system will be established by the COTR with input from the Contractor. The Work Assignment system will operate within the following general guidelines:

a. **Work Assignment (W.A.) Information**

1. All work to be assigned under this contract shall relate directly to one or more of the task areas listed in the Statement of Work.
2. Each W.A. shall be written for the conduct of a specific, finite task.
3. Each new W.A. shall be numbered serially beginning with 01.
4. Each W.A. shall be completed on the form entitled "Sample Contract Work Assignment" and listed as an Attachment in Section J of this contract.
5. Upon award of the contract, an Administrative Work Assignment as shown in SECTION J, Attachments, shall be issued on a yearly basis. This Work Assignment will cover the time and expenditures necessary for the administration of the contract.

b. **Initiation of a W.A.**

1. The COTR will initiate Part I of the W.A.
2. The Contractor shall complete Part II and obtain the appropriate signature. The Contractor shall forward the proposed W.A. to the COTR.
3. Upon receipt of the proposed W.A. and after determining that the proposed W.A. is acceptable, the COTR will sign Part II to indicate recommendation for approval and forward to the Contracting Officer.
4. Upon receipt, the Contracting Officer will review the proposed W.A.
    a. If approved, the Contracting Officer will sign Part II to indicate approval and will forward the W.A. to the Contractor with a copy to the COTR.
    b. If not approved, the Contracting Officer will notify the COTR, stating the reasons for disapproval.
5. After receipt of the approved W.A., the Contractor shall begin work. The period of performance shall never precede the Contracting Officer Approval date.

c. **Modification to a W.A.**

1. Each amendment to an existing Work Assignment shall contain the original W.A. number and shall designate a modification number. Modification numbers for each W.A. shall be serially numbered beginning with 01 (for example, Work Assignment 01, Modification No. 01).
2. Each W.A. modification shall set forth in specific detail which portion(s) of the W.A. is to be modified. All Cost/Labor modifications shall be in the following format:

	Authorized to Date	**This Modification**	**Revised Estimate**
Labor Hours			
Cost Elements			
(List Each Element)			

d. **Conclusion of a W.A.**

1. For each W.A. performed, the Contractor shall prepare PART III of the Work Assignment for submission to the Contracting Officer.
2. This PART III submission shall include all actual information (cost, effort, and deliverables) relative to the W.A.
3. PART III of the W.A. shall be submitted as soon as possible and not to exceed three months after the closing date of the W.A. For those Work Assignments which expire within three months prior to the contract expiration date, PART III of the Work Assignment shall be submitted on the final contract day.
4. After verification that all work is complete and deliverables have been received and accepted, the COTR will sign Part III of the W.A. to indicate recommendation for approval and forward the W.A. to the Contracting Officer.
5. After verification that the W.A. has been satisfactorily completed, the Contracting Officer will approve completion of the W.A. by signing Part III of the W.A. and forward to the Contractor.

ARTICLE G.4. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

a. Invoice/Financing Request Instructions and Contract Financial Reporting for NIH Cost-Reimbursement Type Contracts NIH(RC)-4 are attached and made part of this contract. The Contractor shall follow the attached instructions and submission procedures specified below to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment.

1. Payment requests shall be submitted to the offices identified below. **Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your payment request unless specified elsewhere in the contract or requested by the Contracting Officer.**

   a. The original invoice shall be submitted to the following **designated billing office**:

      National Institutes of Health
      Office of Financial Management
      Commercial Accounts
      2115 East Jefferson Street, Room 4B-432, MSC 8500
      Bethesda, MD 20892-8500

   b. One copy of the invoice shall be submitted to the following **approving official**:

      Contracting Officer
      Office of Acquisitions
      National Cancer Institute
      Executive Plaza South Room 6002
      6120 Executive Blvd. MSC 7195
      Bethesda, Maryland 20892- 7195

      E-Mail:

      The Contractor shall submit an electronic copy of the payment request to the approving official instead of a paper copy. The payment request shall be transmitted as an attachment via e-mail to the address listed above in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contractor's name, contract number, and unique invoice number.
      [Note: The original payment request must still be submitted in hard copy and mailed to the designated billing office to meet the requirements of a "proper invoice."]

2. In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all payment requests:

    a. Name of the Office of Acquisitions. The Office of Acquisitions for this contract is National Cancer Institute .

    b. Central Point of Distribution. For the purpose of this contract, the Central Point of Distribution is NCI OA Branch B - ncibranchbinvoices@mail.nih.gov .

    c. Federal Taxpayer Identification Number (TIN). If the Contractor does not have a valid TIN, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.

    d. DUNS or DUNS+4 Number. The DUNS number must identify the Contractor's name and address exactly as stated in the contract and as registered in the Central Contractor Registration (CCR) database. If the Contractor does not have a valid DUNS number, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. [*Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.

    e. Invoice Matching Option. This contract requires a two-way match.

    f. Unique Invoice Number. Each payment request must be identified by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization.

b. Inquiries regarding payment of invoices shall be directed to the designated billing office, (301) 496-6452.

c. The Contractor shall include the following certification on every invoice for reimbursable costs incurred with Fiscal Year funds subject to the SALARY RATE LIMITATION LEGISLATION PROVISIONS Article in SECTION H of this contract. For billing purposes, certified invoices are required for the billing period during which the applicable Fiscal Year funds were initially charged through the final billing period utilizing the applicable Fiscal Year funds:

    "I hereby certify that the salaries charged in this invoice are in compliance with the SALARY RATE LIMITATION LEGISLATION PROVISIONS Article in SECTION H of the above referenced contract."

ARTICLE G.5. GOVERNMENT PROPERTY

If this RFP will result in the acquisition or use of Government Property provided by the contracting agency or if the Contracting Officer authorizes in the preaward negotiation process, the acquisition of property (other than real property), this ARTICLE will include applicable provisions and incorporate the HHS Publication, entitled, "HHS Contracting Guide for Contract of Government Property," which can be found at:

http://rcb.cancer.gov/rcb-internet/reference/Appendix Q_HHS Contracting Guide.pdf.

ARTICLE G.6. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

Interim and final evaluations of Contractor performance will be prepared on this contract in accordance with FAR Subpart 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, an interim evaluation will be prepared as determined by the Contracting Officer and the Contracting Officer's Technical Representative .

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer, whose decision will be final.

Copies of the evaluations, Contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

b. Electronic Access to Contractor Performance Evaluations

Contractors may access evaluations through a secure Web site for review and comment at the following address:

https://www.cpars.csd.disa.mil

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. PROTECTION OF HUMAN SUBJECTS, HHSAR 352.270-4(b) (January 2006)

a. The Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR Part 46 and with the Contractor's current Assurance of Compliance on file with the Office for Human Research Protections (OHRP), Department of Health and Human Services. The Contractor further agrees to provide certification at least annually that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects in accordance with 45 CFR Part 46 and the Assurance of Compliance.

b. The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract and shall ensure that work is conducted in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. The Contractor shall not deem anything in this contract to constitute the Contractor or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the Government. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent contractor without imputing liability on the part of the Government for the acts of the Contractor or its employees.

c. If at any time during the performance of this contract, the Contracting Officer determines, in consultation with OHRP that the Contractor is not in compliance with any of the requirements and/or standards stated in paragraphs (a) and (b) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. The Contracting Officer may communicate the notice of suspension by telephone with confirmation in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, after consultation with OHRP, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those contractors with approved Human Subject Assurances.

(End of clause)

ARTICLE H.2. REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS

NIH policy requires education on the protection of human subject participants for all investigators receiving NIH contract awards for research involving human subjects. For a complete description of the NIH Policy announcement

on required education in the protection of human subject participants, the Contractor should access the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.

The information below is a summary of the NIH Policy Announcement:

The Contractor shall maintain the following information: (1) a list of the names and titles of the principal investigator and any other individuals working under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program(s) in the protection of human subjects that has been completed for each named personnel and; (3) a one sentence description of the educational program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Prior to any substitution of the Principal Investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the Contractor shall provide the following written information to the Contracting Officer: the title of the education program and a one sentence description of the program that has been completed by the replacement.

ARTICLE H.3. DATA AND SAFETY MONITORING IN CLINICAL TRIALS

The Contractor is directed to the full text of the NIH Policy regarding Data and Safety Monitoring and Reporting of Adverse Events, which may be found at the following web sites:

http://grants.nih.gov/grants/guide/notice-files/not98-084.html
http://grants.nih.gov/grants/guide/notice-files/not99-107.html
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html

The Contractor must comply with the NIH Policy cited in these NIH Announcements and any other data and safety monitoring requirements found elsewhere in this contract.

Data and Safety Monitoring shall be performed in accordance with the approved Data and Safety Monitoring Plan.

The Data and Safety Monitoring Plan shall be established and approved prior to beginning the conduct of the clinical trial.

ARTICLE H.4. REGISTRATION AND RESULTS REPORTING FOR APPLICABLE CLINICAL TRIALS IN CLINICALTRIALS.GOV

The Food and Drug Administration Amendments Act of 2007 (FDAAA) at: http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ085.110.pdf, Title VIII, expands the National Institutes of Health's (NIH's) clinical trials registry and results database known as ClinicalTrials.gov and imposes new requirements that apply to specified "applicable clinical trials," including those supported in whole or in part by NIH funds. FDAAA requires:

- the registration of certain "applicable clinical trials" (see Definitions at: http://grants.nih.gov/ClinicalTrials_fdaaa/definitions.htm) in ClinicalTrials.gov no later than 21 days after the first subject is enrolled; and
- the reporting of summary results information (including adverse events) no later than 1 year after the completion date (See Definitions at link above) for registered applicable clinical trials involving drugs that are approved under section 505 of the Food, Drug and Cosmetic Act (FDCA) or licensed under section 351 of the PHS Act, biologics, or of devices that are cleared under section 510k of FDCA.

In addition, the Contractor shall notify the Contracting Officer's Technical Representative (COTR), with the trial registration number (NCT number), once the registration is accomplished. This notification may be included in the Technical Progress Report covering the period in which registration occurred, or as a stand alone notification.

The Government, the Contractor, or the Government's delegate may be designated as the sponsor, therefore the "Responsible Party" for the purposes of compliance with FDAAA, which includes registration (and results reporting, if required) of applicable clinical trial(s) performed under this contract in the Government database, ClinicalTrials.gov (http://www.ClinicalTrials.gov) will be defined per protocol.

Additional information is available at: http://prsinfo.clinicaltrials.gov .

ARTICLE H.5. HUMAN MATERIALS

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

ARTICLE H.6. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

The Contractor shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this contract, by collaborating sites, or by subcontractors identified under this contract, were obtained with prior approval by the Office for Human Research Protections (OHRP) of an Assurance to comply with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP-approved Assurances, whether domestic or foreign, and compliance must be ensured by the Contractor.

Provision by the Contractor to the Contracting Officer of a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310), certifying IRB review and approval of the protocol from which the human materials were obtained constitutes the written documentation required. The human subject certification can be met by submission of a self designated form, provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310).

ARTICLE H.7. SALARY RATE LIMITATION, HHSAR 352.231-70 (January 2010)

a. Pursuant to the current and applicable prior HHS appropriations acts, the Contractor shall not use contract funds to pay the direct salary of an individual at a rate in excess of the Federal Executive Schedule Level I in effect on the date an expense is incurred.

b. For purposes of the salary rate limitation, the terms "direct salary," "salary," and "institutional base salary" have the same meaning and are collectively referred to as "direct salary" in this clause. An individual's direct salary is the annual compensation that the Contractor pays for an individual's direct effort (costs) under the contract. Direct salary excludes any income that an individual may be permitted to earn outside of duties to the Contractor. Direct salary also excludes fringe benefits, overhead, and general and administrative expenses (also referred to as indirect costs or facilities and administrative [F&A] costs).

   Note: The salary rate limitation does not restrict the salary that an organization may pay an individual working under an HHS contract or order; it merely limits the portion of that salary that may be paid with Federal funds.

c. The salary rate limitation also applies to individuals under subcontracts. If this is a multiple-year contract or order, it may be subject to unilateral modification by the Contracting Officer to ensure that an individual is not paid at a rate that exceeds the salary rate limitation provision established in the HHS appropriations act in effect when the expense is incurred regardless of the rate initially used to establish contract or order funding.

d. See the salaries and wages pay tables on the U.S. Office of Personnel Management Web site for Federal Executive Schedule salary levels that apply to the current and prior periods.

(End of clause)

See the following Web site for Executive Schedule rates of pay: http://www.opm.gov/oca/.

(For current year rates, click on Salaries and Wages / Executive Schedule / Rates of Pay for the Executive Schedule. For prior year rates, click on Salaries and Wages / select Another Year at the top of the page / Executive Schedule / Rates of Pay for the Executive Schedule. Rates are effective January 1 of each calendar year unless otherwise noted.)

ARTICLE H.8. NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH

NIH-funded investigators shall submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript, upon acceptance for publication, resulting from research supported in whole or in part with direct costs from NIH. NIH defines the author's final manuscript as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. The PMC archive will preserve permanently these manuscripts for use by the public, health care providers, educators, scientists, and NIH. The Policy directs electronic submissions to the NIH/NLM/PMC: http://www.pubmedcentral.nih.gov.

Additional information is available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html.

ARTICLE H.9. NEEDLE DISTRIBUTION

The Contractor shall not use contract funds to distribute any needle or syringe for the purpose of preventing the spread of blood borne pathogens in any location that has been determined by authorities to be inappropriate for such distribution.

ARTICLE H.10. PRESS RELEASES

The Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

ARTICLE H.11. RESTRICTION ON ABORTIONS

The Contractor shall not use contract funds for any abortion.

ARTICLE H.12. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

The Contractor shall not use contract funds for (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

Additionally, in accordance with a March 4, 1997 Presidential Memorandum, Federal funds may not be used for cloning of human beings.

ARTICLE H.13. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING SCIENTIFIC INFORMATION

The Contractor shall not use contract funds to disseminate scientific information that is deliberately false or misleading.

ARTICLE H.14. RESTRICTION ON EMPLOYMENT OF UNAUTHORIZED ALIEN WORKERS

The Contractor shall not use contract funds to employ workers described in section 274A(h)(3) of the Immigration and Nationality Act, which reads as follows:

> "(3) Definition of unauthorized alien. - As used in this section, the term 'unauthorized alien' means, with respect to the employment of an alien at a particular time, that the alien is not at that time either (A) an alien lawfully admitted for permanent residence, or (B) authorized to be so employed by this Act or by the Attorney General."

ARTICLE H.15. MULTIPLE PRINCIPAL INVESTIGATORS

The NIH awarded this contract as a multiple Principal Investigators project. The Key Personnel Article in SECTION G of this contract designates the Contact Principal Investigator and all other Principal Investigators.

Contracts designating multiple Principal Investigators require a current Leadership Plan with updates as needed. The Contractor's Leadership Plan, dated _____, (and as modified thereafter, in accordance with the Reporting Requirements Article in SECTION C of this contract), is hereby incorporated by reference.

ARTICLE H.16. PRIVACY ACT, HHSAR 352.224-70 (January 2006)

This contract requires the Contractor to perform one or more of the following: (a) Design; (b) develop; or (c) operate a Federal agency system of records to accomplish an agency function in accordance with the Privacy Act of 1974 (Act) (5 U.S.C. 552a(m)(1)) and applicable agency regulations. The term "system of records" means a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual. Violations of the Act by the Contractor and/or its employees may result in the imposition of criminal penalties (5 U.S.C. 552a(i)). The Contractor shall ensure that each of its employees knows the prescribed rules of conduct and that each employee is aware that he/she is subject to criminal penalties for violation of the Act to the same extent as Department of Health and Human Services employees. These provisions also apply to all subcontracts the Contractor awards under this contract which require the design, development or operation of the designated system(s) of records [5 U.S.C. 552a(m)(1)]. The contract work statement: (a) identifies the system(s) of records and the design, development, or operation work the Contractor is to perform; and (b) specifies the disposition to be made of such records upon completion of contract performance.

(End of clause)

45 CFR Part 5b contains additional information which includes the rules of conduct and other Privacy Act requirements and can be found at: http://www.access.gpo.gov/nara/cfr/waisidx_06/45cfr5b_06.html.

The Privacy Act System of Records applicable to this project is Number 09-25-0200. This document is incorporated into this contract as an Attachment in SECTION J of this contract. This document is also available at: http://oma.od.nih.gov/ms/privacy/pa-files/read02systems.htm.

ARTICLE H.17. OMB CLEARANCE

In accordance with HHSAR 352.201-70, Paperwork Reduction Act, the Contractor shall not proceed with surveys or interviews until such time as Office of Management and Budget (OMB) Clearance for conducting interviews has been obtained by the Contracting Officer's Technical Representative (COTR) and the Contracting Officer has issued written approval to proceed.

ARTICLE H.18. OPTION PROVISION

Unless the Government exercises its option pursuant to the Option Clause set forth in ARTICLE I.3., the contract will consist only of the Base Period of the Statement of Work as defined in Sections C and F of the contract. Pursuant to FAR Clause 52.217-9, Option to Extend the Term of the Contract and FAR Clause 52.217-6, Option for Increased Quantity set forth in ARTICLE I.3. of this contract, the Government may, by unilateral contract modification, require the Contractor to perform additional options set forth in the Statement of Work and also defined in Sections C and F of the contract. If the Government exercises this option, notice must be given at least 60 days prior to the expiration date of this contract, and the estimated cost [plus fixed fee] of the contract will be increased as set forth in the ESTIMATED COST [PLUS FIXED FEE] Article in SECTION B of this contract.

ARTICLE H.19. SUBCONTRACTING PROVISIONS

a. **Small Business Subcontracting Plan**

1. The Small Business Subcontracting Plan, dated _____ is attached hereto and made a part of this contract.

2. The failure of any Contractor or subcontractor to comply in good faith with FAR Clause 52.219-8, entitled "Utilization of Small Business Concerns" incorporated in this contract and the attached Subcontracting Plan, will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, "Liquidated Damages-Subcontracting Plan."

b. **Subcontracting Reports**

The Contractor shall submit the following Subcontracting reports electronically via the "electronic Subcontracting Reporting System (eSRS) at http://www.esrs.gov.

1. Individual Subcontract Reports (ISR)

   Regardless of the effective date of this contract, the Report shall be due on the following dates for the entire life of this contract:

   April 30th
   October 30th
   Expiration Date of Contract

2. Summary Subcontract Report (SSR)

   Regardless of the effective date of this contract, the Summary Subcontract Report shall be submitted annually on the following date for the entire life of this contract:

   October 30th

For both the Individual and Summary Subcontract Reports, the Contracting Officer shall be included as a contact for notification purposes at the following e-mail address:

TBD
Contracting Officer

ARTICLE H.20. INFORMATION AND PHYSICAL ACCESS SECURITY

A. **HHS-Controlled Facilities and Information Systems Security**

a. To perform the work specified herein, Contractor personnel are expected to have routine (1) physical access to an HHS-controlled facility; (2) physical access to an HHS-controlled information system; (3) access to sensitive HHS data or information, whether in an HHS-controlled information system or in hard copy; or (4) any combination of circumstances (1) through (3).

b. To gain routine physical access to an HHS-controlled information system, and/or access to sensitive data or information, the Contractor and its employees shall comply with Homeland Security Presidential Directive (HSPD)-12, Policy for a Common Identification Standard for Federal Employees and Contractors; Office of Management and Budget Memorandum (M-05-24); and Federal Information Processing Standards Publication (FIPS PUB) Number 201; and with the personal identity verification and investigations procedures contained in the following documents:

1. HHS Information Security Program Policy (http://www.hhs.gov/read/irmpolicy/121504.html)
2. HHS Office of Security and Drug Testing, Personnel Security/Suitability Handbook, dated February 1, 2005 (http://www.hhs.gov/ohr/manual/pssh.pdf)
3. HHS HSPD-12 Policy Document, v. 2.0 (http://www.whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy2005/m05-24.pdf)
4. Information regarding background checks/badges (http://idbadge.nih.gov/background/index.asp)

c. Position Sensitivity Levels:

This contract will entail the following position sensitivity levels:

[ ] **Level 6: Public Trust - High Risk.** Contractor/subcontractor employees assigned to Level 6 positions shall undergo a Suitability Determination and Background Investigation (MBI).

[X] **Level 5: Public Trust - Moderate Risk.** Contractor/subcontractor employees assigned to Level 5 positions with no previous investigation and approval shall undergo a Suitability Determination and a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI).

[X] **Level 1: Non-Sensitive.** Contractor/subcontractor employees assigned to Level 1 positions shall undergo a Suitability Determination and National Check and Inquiry Investigation (NACI).

d. The personnel investigation procedures for Contractor personnel require that the Contractor prepare and submit background check/investigation forms based on the type of investigation required. The minimum Government investigation for a non-sensitive position is a National Agency Check and Inquiries (NACI) with fingerprinting. More restricted positions - i.e., those above non-sensitive, require more extensive documentation and investigation.

The Contractor shall submit a roster, by name, position, e-mail address, phone number and responsibility, of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access and/or maintain a Federal Information System(s). The roster shall be submitted to the Contracting Officer's Technical Representative (COTR), with a copy to the Contracting Officer, within 14 calendar days after the effective date of the contract. The Contracting Officer shall notify the Contractor of the appropriate level of suitability investigations to be performed. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for contractor use at: http://ocio.nih.gov/docs/public/Suitability-roster.xls.

Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification.

The Contractor shall notify the Contracting Officer in advance when any new personnel, who are subject to a background check/investigation, will work under the contract and if they have previously been the subject of national agency checks or background investigations.

All contractor and subcontractor employees shall comply with the conditions established for their designated position sensitivity level prior to performing any work under this contract.

Contractors may begin work after the fingerprint check has been completed.

e. Investigations are expensive and may delay performance, regardless of the outcome of the investigation. Delays associated with rejections and consequent re-investigations may not be excusable in accordance with the FAR clause, Excusable Delays - see FAR 52.249-14. Accordingly, the Contractor shall ensure that any additional employees whose names it submits for work under this contract have a reasonable chance for approval.

f. Typically, the Government investigates personnel at no cost to the Contractor. However, multiple investigations for the same position may, at the Contracting Officer's discretion, justify reduction(s) in the contract price of no more that the cost of the additional investigation(s).

g. The Contractor shall include language similar to this "HHS Controlled Facilities and Information Systems Security" language in all subcontracts that require subcontractor personnel to have the same frequency and duration of (1) physical access to an HHS-controlled facility; (2) logical access to an HHS-controlled information system; (3) access to sensitive HHS data/information, whether in an HHS-controlled information system or in hard copy; or (4) any combination of circumstances (1) through (3).

h. The Contractor shall direct inquiries, including requests for forms and assistance, to the Contracting Officer or designee.

i. Within 7 calendar days after the Government's final acceptance of the work under this contract, or upon termination of the contract, the Contractor shall return all identification badges to the Contracting Officer or designee.

B. **Standard for Security Configurations, HHSAR 352.239-70,** (January 2010)

a. The Contractor shall configure its computers that contain HHS data with the applicable Federal Desktop Core Configuration (FDCC) (see http://nvd.nist.gov/fdcc/index.cfm) and ensure that its computers have and maintain the latest operating system patch level and anti-virus software level.

Note: FDCC is applicable to all computing systems using Windows XPTM and Windows VistaTM, including desktops and laptops - regardless of function - but not including servers.

b. The Contractor shall apply approved security configurations to information technology (IT) that is used to process information on behalf of HHS. The following security configuration requirements apply:
FDCC

c. The Contractor shall ensure IT applications operated on behalf of HHS are fully functional and operate correctly on systems configured in accordance with the above configuration requirements. The Contractor shall use Security Content Automation Protocol (SCAP)-validated tools with FDCC Scanner capability to ensure its products operate correctly with FDCC configurations and do not alter FDCC settings - see http://nvd.nist.gov/validation.cfm. The Contractor shall test applicable product versions with all relevant and current updates and patches installed. The Contractor shall ensure currently supported versions of information technology products met the latest FDCC major version and subsequent major versions.

d. The Contractor shall ensure IT applications designed for end users run in the standard user context without requiring elevated administrative privileges.

e. The Contractor shall ensure hardware and software installation, operation, maintenance, update, and patching will not alter the configuration settings or requirements specified above.

f. The Contractor shall (1) include Federal Information Processing Standard (FIPS) 201-compliant (see http://csrc.nist.gov/publications/fips/fips201-1/FIPS-201-1-chng1.pdf), Homeland Security Presidential Directive

12 (HSPD-12) card readers with the purchase of servers, desktops, and laptops; and (2) comply with FAR Subpart 4.13, Personal Identity Verification.

g. The Contractor shall ensure that its subcontractors (at all tiers) which perform work under this contract comply with the requirements contained in this clause.

C. **Standard for Encryption language, HHSAR 352.239-71,** (January 2010)

a. The Contractor shall use Federal Information processing Standard (FIPS) 140-2-compliant encryption (Security) Requirements for Cryptographic Module, as amended) to protect all instances of HHS sensitive information during storage and transmission. (Note: The Government has determined that HHS information under this contract is considered "sensitive" in accordance with FIPS 199, Standards for Security Categorization of Federal Information and Information Systems, dated February 2004).

b. The Contractor shall verify that the selected encryption product has been validated under the Cryptographic Module Validation Program (see http://csrc.nist.gov/cryptval/) to confirm compliance with FIPS 140-2 (as amended). The Contractor shall provide a written copy of the validation documentation to the Contracting Officer and the Contracting Officer's Technical Representative.

c. The Contractor shall use the Key Management Key (see FIPS 201, Chapter 4, as amended) on the HHS personal identification verification (PIV) card; or alternatively, the Contractor shall establish and use a key recovery mechanism to ensure the ability for authorized personnel to decrypt and recover all encrypted information (see http://csrc.nist.gov/drivers/documents/ombencryption-guidance.pdf). The Contractor shall notify the Contracting Officer and the Contracting Officer's Technical Representative of personnel authorized to decrypt and recover all encrypted information.

d. The Contractor shall securely generate and manage encryption keys to prevent unauthorized decryption of information in accordance with FIPS 140-2 (as amended).

e. The Contractor shall ensure that this standard is incorporated into the Contractor's property management/ control system or establish a separate procedure to account for all laptop computers, desktop computers, and other mobile devices and portable media that store or process sensitive HHS information.

f. The Contractor shall ensure that its subcontractors (all all tiers) which perform work under this contract comply with the requirements contained in this clause.

D. **Additional NIH Requirements**

1. **INFORMATION SECURITY TRAINING**

The contractor shall comply with the below training:

a. Mandatory Training

i. All Contractor employees having access to (1) Federal information or a Federal information system or (2) sensitive data/information as defined at HHSAR 304.1300(a)(4), shall complete the NIH Computer Security Awareness Training course at http://irtsectraining.nih.gov/ before performing any work under this contract. Thereafter, Contractor employees having access to the information identified above shall complete an annual NIH-specified refresher course during the life of this contract. The Contractor shall also ensure subcontractor compliance with this training requirement.

ii. The Contractor shall maintain a listing by name and title of each Contractor/Subcontractor employee working on this contract and having access of the kind in paragraph 1.a(1) above, who has completed the NIH required training. Any additional security training

completed by the Contractor/Subcontractor staff shall be included on this listing. The list shall be provided to the COTR and/or Contracting Officer upon request.

b. Role-based Training

HHS requires role-based training when responsibilities associated with a given role or position, could, upon execution, have the potential to adversely impact the security posture of one or more HHS systems. Read further guidance at Secure One HHS Memorandum on Role-Based Training Requirement.

For additional information see the following: http://ocio.nih.gov/security/security-communicating.htm#RoleBased.

The Contractor shall maintain a list of all information security training completed by each contractor/subcontractor employee working under this contract. The list shall be provided to the COTR and/or Contracting Officer upon request.

c. Rules of Behavior

The Contractor shall ensure that all employees, including subcontractor employees, comply with the NIH Information Technology General Rules of Behavior (http://ocio.nih.gov/security/nihitrob.html), which are contained in the NIH Information Security Awareness Training Course http://irtsectraining.nih.gov.

2. **PERSONNEL SECURITY RESPONSIBILITIES**

The contractor shall comply with the below personnel security responsibilities:

a. The Contractor shall notify the Contracting officer and the COTR **within five working days** before a new employee assumes a position that requires access to HHS information systems or data, or when an employee with such access stops working on this contract. The Government will initiate a background investigation on new employees assuming a position that requires access to HHS information systems or data, and will stop pending background investigations for employees that no longer work under the contract or no longer have such access.

b. **New contractor employees who have or will have access to HHS information systems or data:** The Contractor shall provide the COTR with the name, position title, e-mail address, and phone number of all new contract employees working under the contract and provide the name, position title and position sensitivity level held by the former incumbent. If an employee is filling a new position, the Contractor shall provide a position description and the Government will determine the appropriate position sensitivity level.

c. **Departing contractor employees:** The Contractor shall provide the COTR with the name, position title, and position sensitivity level held by or pending for departing employees. The Contractor shall perform and document the actions identified in the Contractor Employee Separation Checklist (http://ocio.nih.gov/nihsecurity/Emp-sep-checklist.pdf) when a Contractor/subcontractor employee terminates work under this contract. All documentation shall be made available to the COTR upon request.

d. **Commitment to Protect Non-Public Departmental Information and Data.**

The Contractor, and any subcontractors performing under this contract, shall not release, publish, or disclose non-public Departmental information to unauthorized personnel, and shall

protect such information in accordance with provisions of the following laws and any other pertinent laws and regulations governing the confidentiality of such information:

- 18 U.S.C. 641 (Criminal Code: Public Money, Property or Records)
- 18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information)
- Public Law 96-511 (Paperwork Reduction Act)

Each employee, including subcontractors, having access to non-public Department information under this acquisition shall complete the "Commitment to Protect Non-Public Information - Contractor Employee Agreement" located at: http://ocio.nih.gov/docs/public/Nondisclosure.pdf. A copy of each signed and witnessed Non-Disclosure agreement shall be submitted to the Project Officer/COTR prior to performing any work under this acquisition.

3. **Loss and/or Disclosure of Personally Identifiable Information (PII) - Notification of Data Breach**

The Contractor shall report all suspected or confirmed incidents involving the loss and/or disclosure of PII in electronic or physical form. Notification shall be made to the NIH Incident Response Team (IRT) via email (IRT@mail.nih.gov) within one hour of discovering the incident. The Contractor shall follow up with IRT by completing and submitting one of the applicable two forms below within three (3) work days of incident discovery:

NIH PII Spillage Report at: http://ocio.nih.gov/docs/public/PII_Spillage_Report.doc
NIH Lost or Stolen Assets Report at: http://ocio.nih.gov/docs/public/Lost_or_Stolen.doc

ARTICLE H.21. ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY, HHSAR 352.239-73(b) (January 2010)

a. Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, all electronic and information technology (EIT) products and services developed, acquired, maintained, or used under this contract/order must comply with the "Electronic and Information Technology Accessibility Provisions" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194. Information about Section 508 provisions is available at http://www.section508.gov/. The complete text of Section 508 Final provisions can be accessed at http://www.access-board.gov/sec508/provisions.htm.

b. The Section 508 standards applicable to this contract/order are identified in the Statement of Work. The contractor must provide a written Section 508 conformance certification due at the end of each contract/ order exceeding $100,000 when the contract/order duration is one year or less. If it is determined by the Government that EIT products and services provided by the Contractor do not conform to the described accessibility standards in the Product Assessment Template, remediation of the products or services to the level of conformance specified in the Contractor's Product Assessment Template will be the responsibility of the Contractor at its own expense.

c. In the event of a modification(s) to this contract/order, which adds new EIT products or services or revises the type of, or specifications for, products or services the Contractor is to provide, including EIT deliverables such as electronic documents and reports, the Contracting Officer may require that the contractor submit a completed HHS Section 508 Product Assessment Template to assist the Government in determining that the EIT products or services support Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found under Section 508 policy on the HHS Office on Disability Web site (http://www.hhs.gov/od/).

[(End of HHSAR 352.239-73(b)]

d. Prior to the Contracting Officer exercising an option for a subsequent performance period/additional quantity or adding funding for a subsequent performance period under this contract, as applicable, the Contractor must provide a Section 508 Annual Report to the Contracting Officer and Project Officer. Unless otherwise directed by the Contracting Officer in writing, the Contractor shall provide the cited report in accordance with the following schedule. Instructions for completing the report are available in the Section 508 policy on the HHS Office on

Disability Web site under the heading Vendor Information and Documents. The Contractor's failure to submit a timely and properly completed report may jeopardize the Contracting Officer's exercising an option or adding funding, as applicable.

Schedule for Contractor Submission of Section 508 Annual Report:

Sixty (60) calendar days prior to the end of each contract year.

[End of HHSAR 352.239-73(c)]

ARTICLE H.22. CONFIDENTIALITY OF INFORMATION

a. Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

b. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.

c. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.

e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor should obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

f. Contracting Officer determinations will reflect the result of internal coordination with appropriate program and legal officials.

g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

The following information is covered by this article:

Information related to specific clinical trials, including but not limited to participant-level clinical data, biomarker data, archived specimens, DCP or pharmaceutical company-provided preclinical and clinical information pertaining to specific drugs (e.g., agent solicitations, Investigator Brochures).

ARTICLE H.23. INSTITUTIONAL RESPONSIBILITY REGARDING CONFLICTING INTERESTS OF INVESTIGATORS

The Contractor shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that investigators (defined as the principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded under NIH contracts) will not be biased by any conflicting financial interest. For the purposes of this part relating to financial interests, "Investigator" includes the Investigator's spouse and dependent children. 45 CFR Part 94 is available at the following Web site:

http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr;sid=cfc3d0caac2d06e14935ada5731b763d;rgn=div5;view=text;node=45%3A1.0.1.1.52;idno=45;cc=ecfr

As required by 45 CFR Part 94, the Contractor shall, at a minimum:

a. Maintain a written, enforceable policy on conflict of interest that complies with 45 CFR Part 94 and inform each investigator of the policy, the investigator's reporting responsibilities, and the applicable regulations. The Contractor must take reasonable steps to ensure that investigators working as collaborators or subcontractors comply with the regulations.

b. Designate an official(s) to solicit and review financial disclosure statements from each investigator participating in NIH-funded research. Based on established guidelines consistent with the regulations, the designated official(s) must determine whether a conflict of interest exists, and if so, determine what actions should be taken to manage, reduce, or eliminate such conflict. A conflict of interest exists when the designated official(s) reasonably determines that a *Significant Financial Interest* could directly and significantly affect the design, conduct, or reporting of the NIH-funded research. The Contractor may require the management of other conflicting financial interests in addition to those described in this paragraph, as it deems appropriate. Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests are included in 45 CFR Part 94, under Management of Conflicting Interests.

c. Require all financial disclosures to be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

d. Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the Contractor with respect to each conflicting interest 3 years after final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.

e. Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

If a conflict of interest is identified, the Contractor shall report to the Contracting Officer, the existence of the conflicting interest found. This report shall be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis, within sixty (60) days of that identification.

If the failure of an investigator to comply with the conflict of interest policy has biased the design, conduct, or reporting of the NIH-funded research, the Contractor must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer will take appropriate action or refer the matter to the Contractor for further action, which may include directions to the Contractor on how to maintain appropriate objectivity in the funded research.

The Contracting Officer may at any time inquire into the Contractor's procedures and actions regarding conflicts of interests in NIH-funded research, including a review of all records pertinent to compliance with 45 CFR Part 94. The Contracting Officer may require submission of the records or review them on site. On the basis of this review, the Contracting Officer may decide that a particular conflict of interest will bias the objectivity of the NIH-funded research to such an extent that further corrective action is needed or that the Contractor has not managed, reduced, or eliminated the conflict of interest. The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

If the Contracting Officer determines that NIH-funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an investigator

with a conflict of interest that was not disclosed or managed, the Contractor must require disclosure of the conflict of interest in each public presentation of the results of the research.

ARTICLE H.24. PUBLICATION AND PUBLICITY

In addition to the requirements set forth in HHSAR Clause **352.227-70, Publications and Publicity** incorporated by reference in SECTION I of this contract, the Contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

> "This project has been funded in whole or in part with Federal funds from the National Cancer Institute, National Institutes of Health, Department of Health and Human Services, under Contract No. TBD"

ARTICLE H.25. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477).** All telephone calls will be handled confidentially. The e-mail address is **Htips@os.dhhs.gov** and the mailing address is:

> Office of Inspector General
> Department of Health and Human Services
> TIPS HOTLINE
> P.O. Box 23489
> Washington, D.C. 20026

ARTICLE H.26. YEAR 2000 COMPLIANCE

In accordance with FAR 39.106, Information Technology acquired under this contract must be Year 2000 compliant as set forth in the following clause(s):

1. **Service Involving the Use of Information Technology**
   YEAR 2000 COMPLIANCE--SERVICE INVOLVING THE USE OF INFORMATION TECHNOLOGY

   The Contractor agrees that each item of hardware, software, and firmware used under this contract shall be able to accurately process date data (including, but not limited to, calculating, comparing and sequencing) from, into and between the twentieth and twenty-first centuries and the Year 1999 and the Year 2000 and leap year calculations.

   (End of Clause)

ARTICLE H.27. OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES

Unique research resources arising from NIH-funded research are to be shared with the scientific research community. NIH provides guidance, entitled, "Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice," (Federal Register Notice, December 23, 1999 [64 FR 72090]), concerning the appropriate terms for disseminating and acquiring these research resources. This guidance, found at: http://ott.od.nih.gov/pdfs/64FR72090.pdf is intended to help contractors ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

Note: For the purposes of this Article, the terms, "research tools", "research materials", and "research resources" are used interchangeably and have the same meaning.

ARTICLE H.28. CONSTITUTION DAY

Each educational institution that receives Federal funds for a fiscal year shall hold an educational program on the United States Constitution on September 17 of such year for the students serviced by the educational institution in accordance with Public Law 108-447.

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

THE FOLLOWING ARTICLE I.1. GENERAL CLAUSE LISTING(S) WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSE LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP:

The complete listing of these clauses may be accessed at:
http://rcb.cancer.gov/rcb-internet/appl/general-clauses/clausesDGS.jsp

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT CONTRACT WITH EDUCATIONAL INSTITUTIONS

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT CONTRACT WITH NON-PROFIT ORGANIZATIONS OTHER THAN EDUCATIONAL INSTITUTIONS

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

Any authorized substitutions and/or modifications other than the General Clauses which will be based on the type of contract/Contractor will be determined during negotiations.

It is expected that the following substitution(s) will be made part of the resultant contract:

a. **Alternate IV** (October 2010) of FAR Clause **52.215-21, Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data--Modifications** (October 2010) is added.

b. **Alternate II** (October 2001) of FAR Clause **52.219-9, Small Business Subcontracting Plan** (January 2011) is added.

c. FAR Clause **52.232-20, Limitation Of Cost** (April 1984), is deleted in its entirety and FAR Clause **52.232-22, Limitation Of Funds** (April 1984) is substituted therefor. **[NOTE: When this contract is fully funded, FAR Clause 52.232-22, LIMITATION OF FUNDS will no longer apply and FAR Clause 52.232-20, LIMITATION OF COST will become applicable.]**

d. **Alternate I** (June 2010) of FAR Clause **52.244-6, Subcontracts for Commercial Items** (December 2010) is added.

e. FAR Clauses **52.249-6, Termination (Cost-Reimbursement)** (May 2004) and **52.249-14, Excusable Delays** (April 1984), are deleted in their entirety and FAR Clause **52.249-5, Termination for Convenience of the Government (Educational and Other Nonprofit Institutions)** (September 1996), is substituted therefore.

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses by reference, (unless otherwise noted), with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

1. FAR Clause **52.203-13, Contractor Code of Business Ethics and Conduct** (April 2010).

2. FAR Clause **52.203-14, Display of Hotline Poster(s)** (December 2007).

   ".....(3) Any required posters may be obtained as follows:

Poster(s)	Obtain From"
HHS Contractor Code of Ethics and Business Conduct Poster	http://oig.hhs.gov/fraud/hotline/OIG_Hotline_Poster.pdf

3. FAR Clause **52.216-15, Predetermined Indirect Cost Rates** (April 1998).

4. FAR Clause **52.217-7, Option for Increased Quantity - Separately Priced Line Item** (March 1989).

   "....The Contracting Officer may exercise the option by written notice to the Contractor within _____ [INSERT THE PERIOD OF TIME IN WHICH THE CONTRACTING OFFICER HAS TO EXERCISE THE OPTION] ...."

5. FAR Clause **52.217-9, Option to Extend the Term of the Contract** (March 2000).

   "(a) The Government may extend the term of this contract by written notice to the Contractor prior to the expiration date of the contract; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 60 days [60 days unless a different number of days is inserted] before the contract expires. The preliminary notice does not commit the Government to an extension."

   "c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed 7 YEARS."

6. FAR Clause **52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns** (July 2005).

   "(c) Waiver of evaluation preference.....
   [ ] Offeror elects to waive the evaluation preference."

7. FAR Clause **52.219-25, Small Disadvantaged Business Participation Program--Disadvantaged Status and Reporting** (December 2010).

8. FAR Clause **52.224-1, Privacy Act Notification** (April 1984).

9. FAR Clause **52.224-2, Privacy Act** (April 1984).

10. **Alternate IV** (December 2007), FAR Clause **52.227-14, Rights in Data - General** (December 2007).

11. **Alternate V** (December 2007), FAR Clause **52.227-14, Rights in Data--General** (December 2007).

Specific data items that are not subject to paragraph (j) include: none

12. FAR Clause **52.227-16, Additional Data Requirements** (June 1987).

13. FAR Clause **52.230-5, Cost Accounting Standards - Educational Institution** (October 2010).

14. FAR Clause **52.230-6, Administration of Cost Accounting Standards** (June 2010).

15. FAR Clause **52.242-3, Penalties for Unallowable Costs** (May 2001).

16. FAR Clause **52.243-2, Changes--Cost Reimbursement** (August 1987), **Alternate V** (April 1984).

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CHAPTER 3) CLAUSES:

1. HHSAR Clause **352.201-70, Paperwork Reduction Act** (January 2006).

2. HHSAR Clause **352.223-70, Safety and Health** (January 2006).

c. NATIONAL INSTITUTES OF HEALTH (NIH) RESEARCH CONTRACTING (RC) CLAUSES:

The following clauses are attached and made a part of this contract:

1. ***NIH (RC)-7, Procurement of Certain Equipment*** *(April 1984).*

2. ***NIH(RC)-11, Research Patient Care Costs*** *(4/1/84).*

ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses in full text.

FEDERAL ACQUISITION REGULATION (FAR)(48 CFR CHAPTER 1) CLAUSES:

a. FAR Clause **52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters** (January 2011)

(a) The Contractor shall update the information in the Federal Awardee Performance and Integrity Information System (FAPIIS) on a semi-annual basis, throughout the life of the contract, by posting the required information in the Central Contractor Registration database at http://www.ccr.gov .

(b) (1) The Contractor will receive notification when the Government posts new information to the Contractor's record.

(2) The Contractor will have an opportunity to post comments regarding information that has been posted by the Government. The comments will be retained as long as the associated information is retained, i.e., for a total period of 6 years. Contractor comments will remain a part of the record unless the Contractor revises them.

(3) (i) Public requests for system information prior to April 15, 2011, will be handled under Freedom of Information Act procedures, including, where appropriate, procedures promulgated under E.O. 12600.

(ii) As required by section 3010 of Public Law 111-212, all information posted in FAPIIS on on or after April 15, 2011, except past performance reviews, will be publicly available.

(End of clause)

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

The following documents are incorporated into this RFP:

SOLICITATION ATTACHMENTS

Attachment No.	Title	Location
Attachment 1:	Packaging and Delivery of Proposal (R & D)	Attachment_1_PACKAGING_AND_DELIVERY_OF_PROPOSA
Attachment 2:	Proposal Intent Response Sheet	http://rcb.cancer.gov/rcb-internet/forms/intent.jsp
Attachment 3:	Statement of Work	Attachment_3_Statement_of_Work.pdf

TECHNICAL PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 4:	Targeted/Planned Enrollment Table, PHS-398/2590 (Rev. 6/09)	http://grants.nih.gov/grants/funding/phs398/enrollment.pdf
Attachment 5:	Technical Proposal Cost Summary	http://funding.niaid.nih.gov/researchfunding/contract/pages/forms.aspx
Attachment 6:	Summary of Related Activities	http://funding.niaid.nih.gov/researchfunding/contract/pages/forms.aspx
Attachment 7:	Protection of Human Subject Assurance Identification/IRB Certification/Declaration of Exemption, OMB Form No. 0990-0263 (Formerly Optional Form 310)	http://www.hhs.gov/ohrp/assurances/forms/of310.rtf
Attachment 8:	HHS Section 508 Product Assessment Template	http://www.hhs.gov/od/vendors/index.html

BUSINESS PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 9:	Proposal Summary and Data Record, NIH-2043	http://funding.niaid.nih.gov/researchfunding/contract/pages/forms.aspx
Attachment 10:	Small Business Subcontracting Plan	http://www.hhs.gov/about/smallbusiness/subcontractplan.html
Attachment 11:	Breakdown of Proposed Estimated Costs (plus fee) w/Excel Spreadsheet	http://oamp.od.nih.gov/contracts/BUSCOST.HTM http://oamp.od.nih.gov/Division/DFAS/spshexcl.xls
Attachment 12:	Offeror's Points of Contact	http://funding.niaid.nih.gov/researchfunding/contract/pages/forms.aspx
Attachment 13:	Disclosure of Lobbying Activities, OMB Form SF-LLL	http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf

INFORMATIONAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 14:	Sample Work Assignment	http://rcb.cancer.gov/rcb-internet/forms/wkassign.pdf
Attachment 15:	Invoice/Financing Request and Contract Financial Reporting Instructions--Cost Reimbursement, NIH(RC)-4	http://rcb.cancer.gov/rcb-internet/forms/rc4.pdf
Attachment 16:	Privacy Act System of Records	http://oma.od.nih.gov/ms/privacy/pa-files/read02systems.htm
Attachment 17:	Safety and Health, HHSAR Clause 352.223-70	http://rcb.cancer.gov/rcb-internet/forms/safety&health-1-06.pdf
Attachment 18:	Procurement of Certain Equipment, NIH(RC)-7	http://funding.niaid.nih.gov/researchfunding/contract/pages/forms.aspx
Attachment 19:	Research Patient Care Costs, NIH(RC)-11	http://funding.niaid.nih.gov/researchfunding/contract/pages/forms.aspx
Attachment 20:	Inclusion Enrollment Report	http://rcb.cancer.gov/rcb-internet/forms/inclusion-enrollment.pdf
Attachment 21:	Commitment to Protect Non-Public Information Contractor Agreement	RFPAttachmentNondisclosure.pdf
Attachment 22:	Roster of Employees Requiring Suitability Investigations	http://ais.nci.nih.gov/forms/Suitability-roster.xls
Attachment 23:	Employee Separation Checklist	http://rcb.cancer.gov/rcb-internet/forms/Emp-sep-checklist.pdf

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST :

1. Go to the **Online Representations and Certifications Application (ORCA)** at: https://orca.bpn.gov/ and complete the Representations and Certifications; and

2. Complete, and **INCLUDE as part of your BUSINESS PROPOSAL:**
   SECTION K - REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS

   which can be accessed electronically from the INTERNET at the following address:
   http://rcb.cancer.gov/rcb-internet/wkf/sectionk.pdf

If you are unable to access this SECTION K - REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. **GENERAL INFORMATION**

a. **INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION** [FAR Provision 52.215-1 (January 2006)]

(a) Definitions. As used in this provision--

"Discussions" are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

"In writing", "writing", or "written" means any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

"Proposal modification" is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

"Proposal revision" is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

"Time," if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

(b) Amendments to solicitations. If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(c) Submission, modification, revision, and withdrawal of proposals.

(1) Unless other methods (e.g., electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(2) The first page of the proposal must show--

(i) The solicitation number;

(ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);

(iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;

(iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and

(v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(3) Submission, modification, revision, and withdrawal of proposals.

(i)Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

(ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--

(1) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or

(2) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or

(3) It is the only proposal received.

(B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.

(iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

(iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

(v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the

identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

(4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.

(5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.

(6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.

(7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.

(8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.

(d) *Offer expiration date*. Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).

(e) *Restriction on disclosure and use of data*.

(1) The proposal submitted in response to this request may contain data (trade secrets; business data (e.g., commercial information, financial information, cost and pricing data); and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following statements, specifying the particular portions of the proposal which are to be restricted:

"Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services (HHS), data contained in the portions of this proposal which the offeror has specifically identified by page number, paragraph, etc. as containing restricted information shall not be used or disclosed except for evaluation purposes.

The offeror acknowledges that HHS may not be able to withhold a record (e.g. data, document, etc.) nor deny access to a record requested pursuant to the Act and that the HHS's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if HHS has determined that disclosure is required by the Act.

If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.

The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (*insert page numbers, paragraph designations, etc. or other identification*)."

(2) In addition, the offeror must mark each page of data it wishes to restrict with the following statement:

"Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."

(3) Offerors are cautioned that proposals submitted with restrictive statements or statements differing in substance from those cited above may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming statement(s).

(f) *Contract award*.

(1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.

(2) The Government may reject any or all proposals if such action is in the Government's interest.

(3) The Government may waive informalities and minor irregularities in proposals received.

(4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

(5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.

(6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.

(7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.

(8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.

(9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.

(10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.

(11) If a post-award debriefing is given to requesting offerors, the Government shall disclose the following information, if applicable:

(i) The agency's evaluation of the significant weak or deficient factors in the debriefed offeror's offer.

(ii) The overall evaluated cost or price and technical rating of the successful and debriefed offeror and past performance information on the debriefed offeror.

(iii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;

(iv) A summary of the rationale for award.

(v) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.

(vi) Reasonable responses to relevant questions posed by the debriefed offeror as to whether source-selection procedures set forth in the solicitation, applicable regulations, and other applicable authorities were followed by the agency.

(End of Provision)

Alternate I (October 1997).As prescribed in 15.209(a)(1), substitute the following paragraph (f)(4) for paragraph (f)(4) of the basic provision:

(f) (4) The Government intends to evaluate proposals and award a contract after conducting discussions with offerors whose proposals have been determined to be within the competitive range. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals. Therefore, the offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.

b. **NAICS CODE AND SIZE STANDARD**

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (See Section K of this RFP), specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

1. The North American Industry Classification System (NAICS) code for this acquisition is 541712.
2. The small business size standard is 500 employees.

THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS. However, the Federal Acquisition Regulation (FAR) requires in every solicitation, (except for foreign acquisitions) the inclusion of the North American Industry Classification System (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

c. **TYPE OF CONTRACT AND NUMBER OF AWARDS**

It is anticipated that multiple awards will be made from this solicitation and that the awards will be made on or about June 16, 2012.

It is anticipated that the awards from this solicitation will be multiple-year Cost-Reimbursement type Completion contracts with a Period of Performance of June 16, 2012 - June 15, 2017, plus two option years and that incremental funding will be used (See Section L.2.c. Business Proposal Instructions).

d. **PRE-PROPOSAL CONFERENCE**

A pre-proposal conference and teleconference will be held with prospective offerors in Rockville, MD on April 27, 2011 from 11:00am to 2:00pm. The location for the conference is 6130 Executive Boulevard, Conference Room J, Rockville, MD 20852. The teleconference number will be provided as an amendment to the RFP approximately 1 week before the conference.The pre-proposal conference will be held for the purpose of providing information concerning the Government's requirements that may be helpful in the preparation of proposals and for answering any questions that you have regarding this solicitation.

The success of this type of conference depends largely on the lead-time available to the Government for research in connection with questions submitted by offerors. Therefore, you are requested to mail or email written questions concerning any areas of uncertainty which, in your opinion, require clarification or correction, in sufficient time to be received on or before April 20, 2011 to the following address:

If hand-delivered or delivery service

Donna Perry-Lalley
Contracting Officer
Office of Acquisitions
National Cancer Institute
Executive Plaza South, Room 6010
6120 Executive Blvd.
Rockville, MD 20852

If using U.S. Postal Service

Donna Perry-Lalley
Contracting Officer
Office of Acquisitions
National Cancer Institute Executive Plaza South, Room 6010
6120 EXECUTIVE BLVD MSC 7195
BETHESDA, MD 20892-7195

The envelope shall be marked, "Pre-proposal conference, RFP No. NCI- N01CN05014-69 ." Alternatively you may email the questions to Donna Perry-Lalley at perryd@mail.nih.gov.

Because of space limitations, each prospective offeror shall be limited to a total of two representatives.

Attendance at the pre-proposal conference is recommended; however, attendance is not a prerequisite for proposal submission and will not be considered a factor in proposal evaluation.

A transcript of the pre-proposal conference, with all questions and answers, will be furnished simultaneously to all prospective offerors whether or not they are in attendance as an amendment to the RFP.

e. **ESTIMATE OF EFFORT**

It is expected that a completion type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the effort to be approximately 78,624 labor hours including all options. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

f. **COMMITMENT OF PUBLIC FUNDS**

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

g. **COMMUNICATIONS PRIOR TO CONTRACT AWARD**

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this RFP. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

h. **RELEASE OF INFORMATION**

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

i. **PREPARATION COSTS**

This RFP does not commit the Government to pay for the preparation and submission of a proposal.

j. **SERVICE OF PROTEST** (SEPTEMBER 2006) - FAR 52.233-2

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the Government Accountability Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Contracting Officer
Office of Acquisitions
National Cancer Institute
EPS, Room 6002
6120 EXECUTIVE BLVD MSC 7195
BETHESDA MD 20892- 7195

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

(End of Provision)

2. **INSTRUCTIONS TO OFFERORS**

a. **GENERAL INSTRUCTIONS**

INTRODUCTION

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

1. **Contract Type and General Clauses**

It is contemplated that a cost-reimbursement, completion type contract will be awarded. (See General Information) Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

2. **Authorized Official and Submission of Proposal**

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addressees, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J hereof. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE

Include RFP title, number, name of organization, DUNS No., identification of the proposal part, and indicate whether the proposal is an original or a copy.

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments.

III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in SECTION J, List of Attachments.

3. **Proposal Summary and Data Record (NIH-2043)**

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See SECTION J, Attachment entitled, PROPOSAL SUMMARY AND DATA RECORD).

4. **Separation of Technical and Business Proposals**

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See SECTION J, Attachment entitled, TECHNICAL PROPOSAL COST SUMMARY.) However, the technical proposal should not include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any), and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

5. **Alternate Proposals**

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

6. **Evaluation of Proposals**

The Government will evaluate proposals in accordance with the factors set forth in PART IV, SECTION M of this RFP.

7. **Potential Award Without Discussions**

The Government reserves the right to award a contract without discussions if the Contracting Officer determines that the initial prices are fair and reasonable and that discussions are not necessary.

8. **Use of the Metric System of Measurement**

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurements, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

Hard Metric - - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).

Soft Metric - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

Dual Systems - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

9. **Standards for Privacy of Individually Identifiable Health Information**

The Department of Health and Human Services (DHHS) issued final modifications to the "Standards for Privacy of Individually Identifiable Health Information," the "Privacy Rule," on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information and is administered and enforced by the DHHS Office for Civil Rights (OCR). Those who must comply with the Privacy Rule (classified under the Rule as "covered entities" must do so by April 14, 2003 (with the exception of small health plans which have an extra year to comply.

Decisions about the applicability and implementation of the Privacy Rule reside with the Contractor and his/her institution. The OCR Web site (http://www.hhs.gov/ocr/) provides information of the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, award, and administration of grants, cooperative agreements and contracts can be found at: http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html.

10. **Privacy Act - Treatment of Proposal Information**

The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

The NIH is requesting the information called for in this RFP pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.

Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract.

Failure to provide any or all of the requested information may result in a less than adequate review.

In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.

Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of NIH contracting

programs. Authority for requesting this information is provided by Section 301 and Title IV of the PHS Act, as amended.

The information provided by you may be routinely disclosed for the following purposes:

- to the cognizant audit agency and the Government Accountability Office for auditing.
- to the Department of Justice as required for litigation.
- to respond to congressional inquiries.
- to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

11. **Selection of Offerors**

a. The acceptability of the scientific and technical portion of each research contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation factors of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.

b. The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.

c. If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.

d. If the Government intends to conduct discussions prior to awarding a contract -

1. Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

   Such communications shall not be used to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or otherwise revise the proposal, but may be considered in rating proposals for the purpose of establishing the competitive range.

2. The Contracting Officer will, in concert with program staff, decide which proposals are in the competitive range. The competitive range will be comprised of all of the most highly rated proposals. Oral or written discussions will be conducted with all offerors in the competitive range.

   While it is NCI's policy to conduct discussions with all offerors in the competitive range, NCI reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected source in accordance with HHSAR 315.370.

e. The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror.

f. The NCI reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet NCI requirements. Synopses of awards exceeding $25,000 will be published in FedBizOpps.

12. **Institutional Responsibility Regarding Conflicting Interests of Investigators**

45 CFR Part 94 promotes objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research to be performed under NIH contracts will be biased by any conflicting financial interest of an Investigator. The Institution shall comply with all requirements of 45 CFR Part 94 at http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr;sid=9f130b6d2d48bb73803ca91ce943be3a;rgn=div5;view=text;node=45%3A1.0.1.1.53;idno=45;cc=ecfr

13. **ROTC Access and Federal Military Recruiting on Campus**

Section 514 of the FY 1997 Appropriations Act prohibits NIH from providing contract funds to educational institutions that the Secretary of Defense determines have a policy or practice (regardless of when implemented) that either prohibits, or in effect prevents (1) the maintaining, establishing, or operation of a unit of the Senior Reserve Officer Training Corps at the covered education entity; or (2) a student at the covered educational entity from enrolling in a unit of the Senior Reserve Officer Training Corps at another institution of higher education.

Further, contract funds may not be provided to educational institutions that have a policy or practice that prohibits or prevents (1) entry to campuses, or access to students (who are 17 years of age or older) on campuses, for purposes of Federal military recruiting; or (2) access by military recruiters for purposes of Federal military recruiting to information pertaining to students (who are 17 years of age or older) enrolled at the covered educational entity.

14. **Past Performance Information**

a. Offerors shall submit the following information as part of their Business proposal.

A list of the last 3 contracts completed during the past Three years and the LAST 3 CONTRACTS AWARDED and currently being performed that are similar in nature to the solicitation workscope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors may also submit past performance information regarding predecessor companies, key personnel who have relevant experience or subcontractors that will perform major or critical aspects of the requirement when such information is relevant to the instant acquisition.
Include the following information for each contract or subcontract listed:

1. Name of Contracting Organization
2. Contract Number (for subcontracts, provide the prime contract number and the subcontract number)
3. Contract Type
4. Total Contract Value
5. Description of Requirement
6. Contracting Officer's Name and Telephone Number
7. Program Manager's Name and Telephone Number
8. North American Industry Classification System (NAICS) Code

The offeror may provide information on problems encountered on the identified contracts and the offeror's corrective actions.

b. The Government is not required to contact all references provided by the offeror. Also, references other than those identified by the offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the offeror's past performance.

15. **Electronic and Information Technology Accessibility, Section 508 Compliance** is applicable to this solicitation and the following information is provided to assist in proposal preparation.

IMPORTANT NOTE TO OFFERORS: The following information shall be addressed in a separate section of the Technical Proposal, entitled, "Section 508 Compliance."

Electronic and Information Technology Accessibility, **HHSAR 352.239-73(a)** (January 2010)

a. Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194), require that, unless an exception applies, all EIT products and services developed, acquired, maintained, or used by any Federal department or agency permit--

i. Federal employees with disabilities to have access to and use information and data that is comparable to the access and use of information and data by Federal employees who are not individuals with disabilities; and

ii. Members of the public with disabilities seeking information or services from a Federal agency to have access to and use of information and data that is comparable to the access and use of information and data by members of the public who are not individuals with disabilities.

b. Accordingly, any vendor submitting a proposal/quotations/bid in response to this solicitation must demonstrate compliance with the established EIT accessibility standards. Information about Section 508 visions is available at http://www.section508.gov/. The complete text of Section 508 Final Provisions can be accessed at http://www.access-board.gov/sec508/provisions.htm.

c. The Section 508 accessibility standards applicable to this solicitation are identified in the Statement of Work/Specification/Performance Work Statement. In order to facilitate the Government's evaluation to determine whether EIT products and services proposed meet applicable Section 508 accessibility standards, offerors must prepare an HHS Section 508 Product Assessment Template, in accordance with its completion instructions, and provide a binding statement of conformance. The purpose of the template is to assist HHS acquisition and program officials in determining that EIT products and services proposed support applicable Section 508 accessibility standards. The template allows vendors or developers to self-evaluate their products or services and document in detail how they do or do not conform to a specific Section 508 standard. Instructions for preparing the HHS Section 508 Product Evaluation Template may be found under Section 508 policy on the HHS Office on Disability Web site (http://www.hhs.gov/od/).

d. Respondents to this solicitation must also provide any additional detailed information necessary for determining applicable Section 508 standards conformance, as well as for documenting EIT products or services that are incidental to the project, which would constitute an exception to Section 508 requirements. If a vendor claims its products or services, including EIT deliverables such as electronic documents and reports, meet applicable Section 508 accessibility standards in its completed HHS Section 508 Product Assessment Template, and it is later determined by the Government -- i.e., after award of a contract/order, that products or services delivered

do not conform to the described accessibility standards in the Product Assessment Template, remediation of the products or services to the level of conformance specified in the vendor's Product Assessment Template will be the responsibility of the Contractor and at its expense.

(End of provision)

The "HHS Section 508 Product Assessment Template" is included in SECTION J - List of Attachments, of this solicitation.

16. **Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (February 1998)**

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: http://www.acquisition.gov/far/index.html.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

a. Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).

b. Limitations on Pass-Through Charges--Identification of Subcontract Effort, FAR Provision 52.215-22, (October 2009).

c. Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), FAR Clause 52.222-24, (February 1999).

b. **TECHNICAL PROPOSAL INSTRUCTIONS**

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

Note to Offerors: Beginning May 25, 2008, the offeror shall include the applicable PubMed Central (PMC) or NIH Manuscript Submission reference number when citing publications that arise from its NIH funded research.

1. **Technical Discussions**

The technical discussion included in the technical proposal should respond to the items set forth below:

a. **Statement of Work**

1. Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project

and your proposed approach. This should support the scope of the project as you perceive it.

2. Approach

   The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives. Proposals which merely restate the requirements of the Government's scope of work will not be eligible for award.

   Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

3. Methods

   Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

4. Schedule

   Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments of work, as applicable, by contract year as well as for the overall contract. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

b. **Personnel**

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

1. Single Principal Investigator/Project Director

   List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the

estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

2. Multiple Principal Investigators

The NIH now provides offerors the opportunity to propose a multiple Principal Investigator (PI) model on research and development contracts. The multiple PI model is intended to supplement, and not replace, the traditional single PI model. The NIH chose this RFP as a candidate for the multiple PI model. Ultimately, the decision to submit a proposal using the multiple PI versus single PI is the decision of the investigators and their institutions. The decision should be consistent with and justified by the scientific goals of the project.

It is essential that organizations consider all aspects of this approach before submitting a proposal. While there are some projects that clearly are appropriate for the multiple PI model, the "fit" of other projects may not be so clear. Offerors should base the selection of either the single PI or multiple PI option on the research proposed, to ensure optimal facilitation of the science. Projects suitable for the multiple PI model could include as few as two PIs who are jointly responsible for the scientific and technical direction of the project. The multiple PI option is based on the proposed project, not on the number of performance sites or the number of participating institutions.

Multiple PIs under research contracts shall use the Subcontract Model. In this approach, offerors submit a single proposal, and a single award is made to the prime contractor. The prime contractor, when appropriate, will award subcontracts to fund the components of the project at the other institutions. The relationship between the contractor and subcontractors must be designed to support all components of the project.

To facilitate communication with the NIH, the offeror must designate a Contact PI at the time of proposal submission. The Contact PI must be employed at the prime contractor's organization. The designation of the Contact PI may rotate on an annual basis. However, this rotation is restricted to PIs located at the prime contractor's organization. The Contact PI is responsible for: relaying communications between all of the PIs and the NIH, and coordinating progress reports for the project. Being named Contact PI does not confer any special authority for the project.

Leadership Plan

Offerors proposing multiple PIs will need to submit a Leadership Plan as part of the Technical Proposal. The Leadership Plan shall describe the governance and organizational structure of the research project including communication plans, process for making decisions on scientific direction, allocation of resources, publications, intellectual property issues, and procedures for resolving conflicts. The Leadership Plan shall follow the Table of Contents provided below:

I. Rationale
   Include a discussion of how the project will be enhanced by the multiple PI approach.

II. Identification of all proposed PIs
   Identify the proposed PIs, their point of contact information and affiliated organizations, and the percentages of time proposed for this project. Identify the Contact PI and plans for rotation of that role, if any.

III. Roles and Responsibilities

Identify both the scientific and administrative roles and responsibilities of all named PIs.

IV. Approach to Fiscal and Management Coordination
Describe how the project will be performed and monitored from a fiscal and management perspective. Discuss organizational administrative coordination and support.

V. Project Direction and Resource Allocation
Address how decisions will be made regarding scientific direction, and, how resources will be allocated and redistributed if needed during performance. Address plans for shared resources such as IT or other shared data considerations. If joint standard operating procedures will be developed, describe this process.

VI. Communication and Lines of Authority
Address communication and lines of authority within and among PIs and within and among organizations.

VII. Data sharing, Intellectual Property, Publication, and other Proprietary Considerations
Data sharing plans, intellectual property considerations, publication agreements, and any other proprietary or confidential information sharing should be addressed in this section.

VIII. Conflict Resolution
Address how conflicts will be avoided, identified, and resolved.

IX. Other
Address any other information relative to the leadership approach to Multiple PI projects.

Offerors submitting single PI proposals do not need to submit a Leadership Plan.

3. Other Investigators

List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

4. Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

- The specific items or expertise they will provide.
- Their availability to the project and the amount of time anticipated.
- Willingness to act as a consultant.
- How rights to publications and patents will be handled.

5. Resumes

   Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

2. **Other Considerations**

   Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

   a. Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.

   b. Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.

   c. Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.

   d. Other factors you feel are important and support your proposed research.

   e. Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

3. **Technical Evaluation**

   Proposals will be technically evaluated in accordance with SECTION M - Evaluation Factors for Award of this solicitation.

4. **Human Subjects**

   IMPORTANT NOTE TO OFFERORS: The following subparagraphs shall be addressed, as applicable, in a SEPARATE SECTION of the Technical Proposal entitled, "HUMAN SUBJECTS."

   a. **Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects, HHSAR 352.270-4(a) (January 2006)**

      a. Copies of the Department of Health and Human Services (HHS) regulations for the protection of human subjects, 45 CFR Part 46, are available from the Office for Human Research Protections (OHRP), Bethesda, Maryland 20892. The regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the HHS.

      b. The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information. The regulations extend to the use of human organs, tissue, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects. The use of autopsy materials is governed by applicable State and local law and is not directly regulated by 45 CFR Part 46.

      c. Activities in which the only involvement of human subjects will be in one or more of the categories set forth in 45 CFR 46.101(b)(1-6) are exempt from coverage.

d. Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal. The Government's Project Officer will make a final determination of whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the proposal. In doubtful cases, the Project Officer will consult with OHRP.

e. In accordance with 45 CFR Part 46, prospective Contractors being considered for award shall be required to file with OHRP an acceptable Assurance of Compliance with the regulations, specifying review procedures and assigning responsibilities for the protection of human subjects. The initial and continuing review of a research project by an institutional review board shall assure that: the rights and welfare of the human subjects involved are adequately protected; the risks to the subjects are reasonable in relation to both the potential benefits, if any, to the subjects and the importance of the knowledge to be gained; and informed consent will be obtained by methods that are adequate and appropriate. HHS regulations for the protection of human subjects (45 CFR Part 46), information regarding OHRP registration and assurance requirements/processes, and OHRP contact information can be accessed at the OHRP Web site (at http://www.hhs.gov/ohrp/).

f. Offerors may consult with OHRP for advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects.

(End of provision)

b. **Instructions to Offerors Regarding Protection of Human Subjects**

Offerors must address the following human subjects protections issues if this contract will be for research involving human subjects (note: under each of the following points below, the offeror should indicate whether the information provided relates to the primary research site, or to a collaborating performance site(s), or to all sites:

a. Risks to the subjects

- Human Subjects Involvement and Characteristics:
  - Describe the proposed involvement of human subjects in response to the solicitation.
  - Describe the characteristics of the subject population, including their anticipated number, age range, and health status.
  - Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as fetuses, pregnant women, children, prisoners, institutionalized individuals, or others who are likely to be vulnerable populations.
- Sources of Materials:
  - Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.
- Potential Risks:
  - Describe the potential risks to subjects (physical, psychological, social, legal, or other) and assess their likelihood and seriousness to the subjects.

- Describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures, to participants in the proposed research, where appropriate.

b. Adequacy of Protection Against Risks

- Recruitment and Informed Consent:
  - Describe plans for the recruitment of subjects and the procedures for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. The informed consent document for the Contractor and any collaborating sites should be submitted only if requested elsewhere in the solicitation. Be aware that an IRB-approved informed consent document for the Contractor and any participating collaborative sites must be provided to the Government prior to patient accrual or participant enrollment.
- Protection Against Risk:
  - Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness.
  - Discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects where appropriate.
  - In studies that involve interventions, describe the provisions for data and safety monitoring of the research to ensure the safety of subjects.

c. Potential Benefits of the Proposed Research to the Subjects and Others

- Discuss the potential benefits of the research to the subjects and others.
- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.
- Describe treatments and procedures that are alternatives to those provided to the participants by the proposed research, where appropriate.

d. Importance of the Knowledge to be Gained

- Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.
- Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that may reasonably be expected to result.

Note: If a test article (investigational new drug, device, or biologic) is involved, name the test article and state whether the 30-day interval between submission of offeror's certification to the Food and Drug Administration (FDA) and its response has elapsed or has been waived and/or whether the FDA has withheld or restricted use of the test article.

Collaborating Site(s)
When research involving human subjects will take place at collaborating site(s) or other performance site(s), the offeror must provide in this section of its proposal a list of the collaborating sites and their assurance numbers. Further, if you are awarded a contract, you must obtain in writing, and keep on file, an assurance from each site that the previous points have been adequately

addressed at a level of attention that is at least as high as that documented at your organization. Site(s) added after an award is made must also adhere to the above requirements.

c. **Required Education in the Protection of Human Research Participants**

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for contracts for research involving human subjects. This policy announcement is found in the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html. Offerors should review the policy announcement prior to submission of their offers. The following is a summary of the Policy Announcement:

For any solicitation for research involving human subjects, the offeror shall provide in its technical proposal the following information: (1) a list of the names of the principal investigator and any other individuals proposed under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program completed (or to be completed prior to the award of the contract) for each named personnel; (3) a one sentence description of the program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Curricula that are readily available and meet the educational requirement include the NIH Office of Extramural Research (OER) on-line tutorial, entitled "Protecting Human Research Participants" at: http://phrp.nihtraining.com . This course is also available in Spanish under the title "Protección de los participantes humanos de la investigación" at: http://pphi.nihtraining.com . You may take the tutorials on-line or download the information in PDF form at no cost. The University of Rochester has made its training program available for individual investigators. Completion of this program will also satisfy the educational requirement. The University of Rochester manual can be obtained through Centerwatch, Inc. at http://store.centerwatch.com/p-51-protecting-study-volunteers-in-research-3rd-edition.aspx .

If an institution already has developed educational programs on the protection of research participants, completion of these programs also will satisfy the educational requirement.

In addition, prior to the substitution of the principal investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the Contractor shall provide the contracting officer with the title of the education program and a one sentence description of the program that the replacement has completed.

d. **Inclusion of Women and Minorities in Research Involving Human Subjects**

It is NIH policy that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects involving human subjects, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant Institute/Center Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. The Director, NIH, may determine that exclusion under other circumstances is acceptable, upon the recommendation of an Institute/Center Director, based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43), **and applies to research subjects of all ages.**

All investigators proposing research involving human subjects should read the UPDATED "NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended October 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 at the following web site:

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm

These guidelines contain a definition of **clinical research** adopted in June 2001, as: "(1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies; (2) Epidemiologic and behavioral studies; and (3) Outcomes research and health services research."

Information Required for ALL Clinical Research Proposals

This solicitation contains a review criterion addressing the adequacy of: (1) the offeror's plans for inclusion of women and minorities in the research proposed; or (2) the offeror's justification(s) for exclusion of one or both groups from the research proposed.

Provide information on the composition of the proposed study population in terms of sex/gender and racial/ethnic groups and provide a rationale for selection of such subjects in response to the requirements of the solicitation. The description may include (but is not limited to) information on the population characteristics of the disease or condition being studied in the planned research, and/or described in the statement of work, national and local demography, knowledge of the racial/ethnic/cultural characteristics of the population, prior experience and collaborations in recruitment and retention of the populations and subpopulations to be studied, and the plans, arrangements and letters of commitment from relevant community groups and organizations for the planned research.

The proposal must include the following information:

- A description of the subject selection criteria
- The proposed dates of enrollment (beginning and end)
- A description of the proposed outreach programs for recruiting women and minorities as subjects
- A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group
- The proposed sample composition using the "Targeted/Planned Enrollment Table"(see Section J, Attachments)

NOTE 1: *For all proposals, use the ethnic and racial categories and complete the "Targeted/Planned Enrollment Table in accordance with the Office of Management and Budget (OMB) Directive No. 15, which may be found at*: http://www.whitehouse.gov/omb/fedreg_notice_15.

Standards for Collecting Data. When you, as a contractor, are planning data collection items on race and ethnicity, you shall use, at a minimum, the categories identified in OMB Directive No. 15. The collection of greater detail is encouraged. However, you should design any additional, more detailed items so that they can be aggregated into these required categories. Self-reporting or self-identification using two separate questions is the preferred method for collecting data on race and ethnicity. When you collect race and

ethnicity separately, you must collect ethnicity first. You shall offer respondents the option of selecting one or more racial designations. When you collect data on race and ethnicity separately, you shall also make provisions to report the number of respondents in each racial category who are Hispanic or Latino. When you present aggregate data, you shall provide the number of respondents who selected only one category, for each of the five racial categories. If you collapse data on multiple responses, you shall make available, at a minimum, the total number of respondents reporting "more than one race." Federal agencies shall not present data on detailed categories if doing so would compromise data quality or confidentiality standards.

Use the form entitled, "Targeted/Planned Enrollment Table," when preparing your response to the solicitation requirements for inclusion of women and minorities. (See Section J-List of Documents, Exhibits and Other Attachments of the RFP) Unless otherwise specified in this solicitation, the Government has determined that the work required by this solicitation does not involve a sex/gender specific study or a single or limited number of minority population groups. Therefore, the NIH believes that the inclusion of women and minority populations is appropriate for this project. (See Section M of this RFP for more information about evaluation factors for award.)

Use the form entitled, "Inclusion Enrollment Report," for reporting in the resultant contract.

e. **Inclusion of Children in Research Involving Human Subjects**

It is NIH policy that children (defined below) must be included in all human subjects research, including, but not limited to, clinical trials, conducted under a contract funded by the NIH, unless there are clear and compelling reasons not to include them. (See examples of Justifications for Exclusion of Children below). For the purposes of this policy, contracts involving human subjects include categories that would otherwise be exempt from the DHHS Policy for Protection of Human Research Subjects (sections 101(b) and 401(b) of 45 CFR 46), such as surveys, evaluation of educational interventions, and studies of existing data or specimens that should include children as participants. This policy applies to both domestic and foreign research contracts.

For purposes of this policy, a child is defined as an individual under the age of 21 years.

All offerors proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" which was published in the NIH Guide for Grants and Contracts on March 6, 1998 and is available at the following URL address:

http://www.nih.gov/grants/guide/notice-files/not98-024.html

Offerors also may obtain copies from the contact person listed in the RFP.

Inclusion of children as participants in research must be in compliance with all applicable subparts of 45 CFR 46 as well as other pertinent laws and regulations whether or not such research is otherwise exempted from 45 CFR 46. Therefore, any proposals must include a description of plans for including children, unless the offeror presents clear and convincing justification for an exclusion. The "Human Subjects" section of your technical proposal should provide either a description of the plans to include children and a rationale for selecting or excluding a specific age range of child, or an explanation of the reason(s) for excluding children as participants in the research. This solicitation contains a review criterion addressing the adequacy of: (1) the plans for including children as appropriate for the scientific goals of the research; and/or (2) the justification of exclusion of children or exclusion of a specific age range of children.

When children are included, the plan also must include a description of: (1) the expertise of the investigative team for dealing with children at the ages included; (2)

the appropriateness of the available facilities to accommodate the children; and, (3) the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation.

Justifications for Exclusion of Children
It is expected that children will be included in all research involving human subjects unless one or more of the following exclusionary circumstances can be fully justified:

- The objective of the solicitation is not relevant to children.
    - There are laws or regulations barring the inclusion of children in the research to be conducted under the solicitation.
    - The knowledge being sought in the research is already available for children or will be obtained from another ongoing study, and an additional study will be redundant. You should provide documentation of other studies justifying the exclusion.
    - A separate, age-specific study in children is warranted and preferable. Examples include:
        - The relative rarity of the condition in children, as compared with adults (in that extraordinary effort would be needed to include children); or
        - The number of children is limited because the majority are already accessed by a nationwide pediatric disease research network; or
        - Issues of study design preclude direct applicability of hypotheses and/ or interventions to both adults and children (including different cognitive, developmental, or disease stages of different age-related metabolic processes); or
        - Insufficient data are available in adults to judge potential risk in children (in which case one of the research objectives could be to obtain sufficient adult data to make this judgment). While children usually should not be the initial group to be involved in research studies, in some instances, the nature and seriousness of the illness may warrant their participation earlier based on careful risk and benefit analysis; or
        - Study designs aimed at collecting additional data on pre-enrolled adult study subjects (e.g., longitudinal follow-up studies that did not include data on children);
        - Other special cases justified by the offeror and found acceptable to the review group and the Institute Director

          Definition of a Child

          For the purpose of this solicitation, a child is defined as an individual under the age of 21 years.

          The definition of child described above will pertain to this solicitation (notwithstanding the FDA definition of a child as an individual from infancy to 16 years of age, and varying definitions employed by some states). Generally, State laws define what constitutes a "child," and such definitions dictate whether or not a person can legally consent to participate in a research study. However, State laws vary, and many do not address when a child can consent to participate in research. Federal Regulations (45 CFR 46, subpart D, Sec.401-409) address DHHS protections for children who participate in research, and rely on State definitions of "child" for consent purposes. Consequently, the children

included in this policy (persons under the age of 21) may differ in the age at which their own consent is required and sufficient to participate in research under State law. For example, some states consider a person age 18 to be an adult and therefore one who can provide consent without parental permission.

Research Involving Prisoners as Subjects

a. HHS Regulations at 45 CFR Part 46, Subpart C provide additional protections pertaining to biomedical and behavioral research involving prisoners or those individuals who, during the period of the contract become prisoners, as subjects. These regulations also set forth the duties of the Institutional Review Board (IRB) where prisoners are involved in the research. HHS funded research involving prisoners as subjects may not proceed until the Office for Human Research Protections (OHRP) issues approval, in writing, as required by 45 CFR 46.306(a)(2). In addition, OHRP Guidance on the Involvement of Prisoners in Research may be found at: http://www.hhs.gov/ohrp/humansubjects/guidance/prisoner.pdf.

b. HHS Waiver for Epidemiological Research Involving Prisoners as Subjects

   On June 20, 2003 the Secretary of HHS waived the applicability of certain provisions of Subpart C of 45 CFR Part 46, (Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects) to specific types of epidemiological research involving prisoners as subjects.

   The applicability of 45 CFR 46.305(a)(1) and 46.306(a)(2) for certain epidemiological research conducted or funded by DHHS is waived when:

   1. The sole purposes are:
      a. to describe the prevalence or incidence of a disease by identifying all cases, or
      b. to study potential risk factor associations for a disease, and
   2. The Institution responsible for the conduct of the research certifies to the OHRP that the Institutional Review Board (IRB) approved the research and fulfilled its duties under 45 CFR 46.305(a)(2 7) and determined and documented that:
      a. the research presents no more than minimal risk, and
      b. no more than inconvenience to the prisoner subjects, and
      c. prisoners are not a particular focus of the research.

      For more information about this Waiver see http://www.hhs.gov/ohrp/special/prisoners/Prisoner waiver 6-20-03.pdf

f. **Research Involving Human Fetal Tissue**

Human Fetal Tissue means tissue or cells obtained from a dead human fetus, including human embryonic stem cells, human pluripotent stem cells and human embryonic germ cells.

The governing federal statute is the Public Health Service Act, 42 U.S.C. 289g 1 and 289g 2. Implementing regulations and guidance for conducting research on human fetal tissue may be found at 45 CFR 46, Subpart B and http://grants1.nih.gov/grants/guide/notice-files/not93-235.html and any subsequent revisions to this NIH Guide to Grants and Contracts ("Guide") Notice.

By signing the face page of the proposal, the offeror (authorized institutional official) certifies that researchers using human fetal tissue are in compliance with 42 USC 289g

2. This statute specifically prohibits any person from knowingly acquiring, receiving, or transferring any human fetal tissue for valuable consideration. "Valuable consideration" is a concept similar to profit, and does not include reasonable payment for costs associated with the collection processing, preservation, storage, quality control or transportation of these tissues.

Research involving the transplantation of human fetal tissue must be conducted in accordance with applicable Federal, State and local law.

g. **Data and Safety Monitoring in Clinical Trials**

All offerors are directed to the full text of the NIH Policies regarding Data and Safety Monitoring and Reporting of Adverse Events that are found in the NIH Guide for Grants and Contracts Announcements at the following web sites:

http://grants.nih.gov/grants/guide/notice-files/not98-084.html
http://grants.nih.gov/grants/guide/notice-files/not99-107.html
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html

All offerors receiving an award under this solicitation must comply with the NIH Policy cited in these NIH Announcements and any other data and safety monitoring requirements found elsewhere in this solicitation.

The following is a brief summary of the Data and Safety Monitoring and Adverse Event Reporting Requirements:

Data and Safety Monitoring is required for every clinical trial. Monitoring must be performed on a regular basis and the conclusions of the monitoring reported to the Contracting Officer's Technical Representative (COTR).

The type of data and safety monitoring required will vary based on the type of clinical trial and the potential risks, complexity and nature of the trial. A plan for data and safety monitoring is required for all clinical trials. A general description of a monitoring plan establishes the overall framework for data and safety monitoring. It should describe the entity that will be responsible for the monitoring, and the policies and procedures for adverse event reporting. Phase III clinical trials generally require the establishment of a Data Safety Monitoring Board (DSMB). The establishment of a DSMB is optional for Phase I and Phase II clinical trials.

The DSMB/Plan is established at the time the protocol is developed and must be approved by both the Institutional Review Board (IRB) and the Government and in place before the trial begins. If the protocol will be developed under the contract awarded from this solicitation, a general description of the data and safety monitoring plan must be submitted as part of the proposal and will be reviewed by the scientific review group (Technical Evaluation Panel, (TEP)) convened to evaluate the proposal. If the protocol is developed and is included as part of the submitted proposal, a complete and specific data and safety monitoring plan must be submitted as part of the proposal.

Monitoring Plans, at a minimum, must include the prompt reporting of adverse events to the IRB, the NIH Office of Biotechnology Activities (OBA), and the Food and Drug Administration (FDA). Also, in the plan you should describe the frequency of reporting of the conclusions of the monitoring activities. The overall elements of each plan may vary depending on the size and complexity of the trial. The NIH Policy for Data and Safety Monitoring at http://grants.nih.gov/grants/guide/notice-files/not98-084.html describes examples of monitoring activities to be considered.

The frequency of monitoring will depend upon potential risks, complexity, and the nature of the trial; therefore a number of options for monitoring trials are available. These can include, but are not limited to, monitoring by a:

- Principal Investigator (required)
- Independent individual /Safety Officer
- Designated medical monitor
- Internal Committee or Board with explicit guidelines
- Data and Safety Monitoring Board (DSMB - required for multisite trials)
- Institutional Review Board (IRB - required)

For multi-site Phase I and Phase II trials, a central reporting entity that will be responsible for preparing timely summary reports of adverse events for distribution among sites and IRBs should be considered.

Organizations with a large number of clinical trials may develop standard monitoring plans for Phase I and Phase II trials. In this case, such organizations may include the IRB-approved monitoring plan as part of the proposal submission.

h. **Registration of and Results Reporting for Applicable Clinical Trials in ClinicalTrials.gov**

The Food and Drug Administration Amendments Act of 2007 (FDAAA) at: http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ085.110.pdf,Title VIII, expands the National Institutes of Health's (NIH's) clinical trials registry and results database known as ClinicalTrials.gov (http://www.clinicaltrials.gov/) and imposes new requirements that apply to certain applicable clinical trials, including those supported in whole or in part by NIH funds. FDAAA requires:

a. The registration of certain "applicable clinical trials" in ClinicalTrials.gov no later than 21 days after the first subject is enrolled; and

b. The reporting of summary results information (including adverse events) no later than 1 year after the completion date for registered applicable clinical trials involving drugs that are approved under section 505 of the Food, Drug and Cosmetic Act (FDCA) or licensed under section 351 of the PHS Act, biologics, or of devices that are cleared under section 510k of FDCA.

The resultant contract will support one or more applicable clinical trial subject to FDAAA.

The "responsible party" is the entity responsible for registering and reporting trial results in ClinicalTrials.gov.

- Where the Contractor is the IND/IDE holder, the Contractor will be considered the Sponsor, therefore the "Responsible Party."
- Where there is no IND/IDE holder or where the Government is the IND/IDE holder, the Government will generally be considered the "Sponsor" and may designate the contractor's Principal Investigator (PI) as the "Responsible Party."
- For Multi-Center trials where there is no IND/IDE holder or where the Government is the IND/IDE holder, the "Responsible Party" will be designated at one site (generally the lead clinical site) and all other sites will be responsible for providing necessary data to the "Responsible Party" for reporting in the database.

Additional information is available at http://prsinfo.clinicaltrials.gov

5. **Obtaining and Disseminating Biomedical Research Resources**

As a public sponsor of biomedical research, the National Institutes of Health (NIH) has a dual interest in accelerating scientific discovery and facilitating product development. Intellectual property restrictions can stifle the broad dissemination of new discoveries and limit future avenues of research and product development. At the same time, reasonable restrictions on the dissemination of research tools are sometimes necessary to protect legitimate proprietary interests and to preserve incentives for commercial development. To assist NIH contractors achieve an appropriate balance, the NIH has provided guidance in the form of a two-part document, consisting of Principles setting forth the fundamental concepts and Guidelines that provide specific information to patent and license professionals and sponsored research administrators for implementation.

The purpose of these Principles and Guidelines is to assist NIH funding recipients in determining: 1) Reasonable terms and conditions for making NIH-funded research resources available to scientists in other institutions in the public and private sectors (disseminating research tools); and 2) Restrictions to accept as a condition of receiving access to research tools for use in NIH-funded research (acquiring research tools). The intent is to help recipients ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

This policy, entitled, "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts," (Federal Register Notice, December 23, 1999 [64 FR 72090] will be included in any contract awarded from this solicitation. It can be found at the following website:

http://ott.od.nih.gov/pdfs/64FR72090.pdf

a. **Sharing Research Data**

[Note: This policy applies to **all** NIH contracts, regardless of dollar value, that are expected to generate research data.]

The NIH endorses the sharing of final research data to expedite the translation of research results into knowledge, products, and procedures to improve human health. This contract is expected to generate research data. Therefore, the offeror must submit a plan in its technical proposal for data sharing or state why data sharing is not possible. If data sharing is limited, the offeror should explain such limitations in its data sharing plan. NIH's data sharing policy may be found at the following Web site:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html

6. **Information and Physical Access Security** is applicable to this solicitation and the following information is provided to assist in proposal preparation.

IMPORTANT NOTE TO OFFERORS: The following information shall be addressed in a separate section of the Technical Proposal entitled "Information Security."

The Homeland Security Presidential Directive (HSPD)-12 and the Federal Information Security Management Act of 2002 (P.L. 107-347) (FISMA) requires each agency to develop, document, and implement an agency-wide information security program to safeguard information and information systems that support the operations and assets of the agency, including those provided or managed by another agency, contractor (including subcontractor), or other source.

A. **HHS-Controlled Facilities and Information Systems Security**

a. To perform the work specified herein, Contractor personnel are expected to have routine (1) physical access to an HHS-controlled facility; (2) physical access to an HHS-controlled information system; (3) access to sensitive HHS data or information, whether in an HHS-controlled information system or in hard copy; or (4) any combination of circumstances (1) through (3).

b. To gain routine physical access to an HHS-controlled information system, and/ or access to sensitive data or information, the Contractor and its employees shall comply with Homeland Security Presidential Directive (HSPD)-12, Policy for a Common Identification Standard for Federal Employees and Contractors; Office of Management and Budget Memorandum (M-05-24); and Federal Information Processing Standards Publication (FIPS PUB) Number 201; and with the personal identity verification and investigations procedures contained in the following documents:

   1. HHS Information Security Program Policy (http://www.hhs.gov/read/ irmpolicy/121504.html)
   2. HHS Office of Security and Drug Testing, Personnel Security/Suitability Handbook, dated February 1, 2005 (http://www.hhs.gov/ohr/manual/pssh.pdf)
   3. HHS HSPD-12 Policy Document, v. 2.0 (http://www.whitehouse.gov/sites/ default/files/omb/assets/omb/memoranda/fy2005/m05-24.pdf)
   4. Information regarding background checks/badges (http://idbadge.nih.gov/background/index.asp)

c. Position Sensitivity Levels:

   This contract will entail the following position sensitivity levels:

   [ ] **Level 6: Public Trust - High Risk.** Contractor/subcontractor employees assigned to Level 6 positions shall undergo a Suitability Determination and Background Investigation (MBI).

   [X] **Level 5: Public Trust - Moderate Risk.** Contractor/subcontractor employees assigned to Level 5 positions with no previous investigation and approval shall undergo a Suitability Determination and a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI).

   [X] **Level 1: Non-Sensitive.** Contractor/subcontractor employees assigned to Level 1 positions shall undergo a Suitability Determination and National Check and Inquiry Investigation (NACI).

d. The personnel investigation procedures for Contractor personnel require that (upon award) the Contractor prepare and submit background check/investigation forms based on the type of investigation required. The minimum Government investigation for a non-sensitive position is a National Agency Check and Inquiries (NACI) with fingerprinting. More restricted positions - i.e., those above non-sensitive, require more extensive documentation and investigation.

   As part of its proposal, and if the anticipated position sensitivity levels are specified in paragraph (d) above, the Offeror shall notify the Contracting Officer of (1) its proposed personnel who will be subject to a background check/investigation and (2) whether any of its proposed personnel who will work under the contract have previously been the subject of national agency checks or background investigations.

Upon award, the Contractor shall submit a roster, by name, position, e-mail address, phone number and responsibility, of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access and/or maintain a Federal Information System(s). The roster shall be submitted to the Contracting Officer's Technical Representative (COTR), with a copy to the Contracting Officer, within 14 calendar days after the effective date of the contract. The Contracting Officer shall notify the Contractor of the appropriate level of suitability investigations to be performed. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for contractor use at: http://ocio.nih.gov/docs/public/Suitability-roster.xls.

Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification.

The Contractor shall notify the Contracting Officer in advance when any new personnel, who are subject to a background check/investigation, will work under the contract and if they have previously been the subject of national agency checks or background investigations.

All contractor and subcontractor employees shall comply with the conditions established for their designated position sensitivity level prior to performing any work under this contract.

Contractors may begin work after the fingerprint check has been completed.

e. Investigations are expensive and may delay performance, regardless of the outcome of the investigation. Delays associated with rejections and consequent re-investigations may not be excusable in accordance with the FAR clause, Excusable Delays - see FAR 52.249-14. Accordingly, the Contractor shall ensure that any additional employees whose names it submits for work under this contract have a reasonable chance for approval.

f. Typically, the Government investigates personnel at no cost to the Contractor. However, multiple investigations for the same position may, at the Contracting Officer's discretion, justify reduction(s) in the contract price of no more than the cost of the additional investigation(s). Accordingly, if position sensitivity levels are specified in paragraph (d) above, the Offeror shall ensure that the employees it proposes for work under this contract/order have a reasonable chance for approval.

g. The Contractor shall include language similar to this "HHS Controlled Facilities and Information Systems Security" language in all subcontracts that require subcontractor personnel to have the same frequency and duration of (1) physical access to an HHS-controlled facility; (2) logical access to an HHS-controlled information system; (3) access to sensitive HHS data/information, whether in an HHS-controlled information system or in hard copy; or (4) any combination of circumstances (1) through (3).

h. The Contractor shall direct inquiries, including requests for forms and assistance, to the Contracting Officer.

i. Within 7 calendar days after the Government's final acceptance of the work under this contract, or upon termination of the contract, the Contractor shall return all identification badges to the Contracting Officer or designee.

B. **Standard for Security Configurations, HHSAR 352.239-70,** (January 2010)

a. The Contractor shall configure its computers that contain HHS data with the applicable Federal Desktop Core Configuration (FDCC) (see http://nvd.nist.gov/fdcc/index.cfm) and ensure that its computers have and maintain the latest operating system patch level and anti-virus software level.

Note: FDCC is applicable to all computing systems using Windows XPTM and Windows VistaTM, including desktops and laptops - regardless of function - but not including servers.

b. The Contractor shall apply approved security configurations to information technology (IT) that is used to process information on behalf of HHS. The following security configuration requirements apply:
FDCC

c. The Contractor shall ensure IT applications operated on behalf of HHS are fully functional and operate correctly on systems configured in accordance with the above configuration requirements. The Contractor shall use Security Content Automation Protocol (SCAP)-validated tools with FDCC Scanner capability to ensure its products operate correctly with FDCC configurations and do not alter FDCC settings - see http://nvd.nist.gov/validation.cfm. The Contractor shall test applicable product versions with all relevant and current updates and patches installed. The Contractor shall ensure currently supported versions of information technology products met the latest FDCC major version and subsequent major versions.

d. The Contractor shall ensure IT applications designed for end users run in the standard user context without requiring elevated administrative privileges.

e. The Contractor shall ensure hardware and software installation, operation, maintenance, update, and patching will not alter the configuration settings or requirements specified above.

f. The Contractor shall (1) include Federal Information Processing Standard (FIPS) 201-compliant (see http://csrc.nist.gov/publications/fips/fips201-1/FIPS-201-1-chng1.pdf), Homeland Security Presidential Directive 12 (HSPD-12) card readers with the purchase of servers, desktops, and laptops; and (2) comply with FAR Subpart 4.13, Personal Identity Verification.

g. The Contractor shall ensure that its subcontractors (at all tiers) which perform work under this contract comply with the requirements contained in this clause.

C. **Standard for Encryption language, HHSAR 352.239-71,** (January 2010)

a. The Contractor shall use Federal Information processing Standard (FIPS) 140-2-compliant encryption (Security) Requirements for Cryptographic Module, as amended) to protect all instances of HHS sensitive information during storage and transmission. (Note: The Government has determined that HHS information under this contract is considered "sensitive" in accordance with FIPS 199, Standards for Security Categorization of Federal Information and Information Systems, dated February 2004).

b. The Contractor shall verify that the selected encryption product has been validated under the Cryptographic Module Validation Program (see http://csrc.nist.gov/cryptval/) to confirm compliance with FIPS 140-2 (as amended). The Contractor shall provide a written copy of the validation documentation to the Contracting Officer and the Contracting Officer's Technical Representative.

c. The Contractor shall use the Key Management Key (see FIPS 201, Chapter 4, as amended) on the HHS personal identification verification (PIV) card; or alternatively, the Contractor shall establish and use a key recovery mechanism to ensure the ability for authorized personnel to decrypt and recover all encrypted information (see http://csrc.nist.gov/drivers/documents/ombencryption-guidance.pdf). The Contractor shall notify the Contracting Officer and the Contracting Officer's Technical Representative of personnel authorized to decrypt and recover all encrypted information.

d. The Contractor shall securely generate and manage encryption keys to prevent unauthorized decryption of information in accordance with FIPS 140-2 (as amended).

e. The Contractor shall ensure that this standard is incorporated into the Contractor's property management/control system or establish a separate procedure to account for all laptop computers, desktop computers, and other mobile devices and portable media that store or process sensitive HHS information.

f. The Contractor shall ensure that its subcontractors (all all tiers) which perform work under this contract comply with the requirements contained in this clause.

D. **Additional NIH Requirements**

1. **INFORMATION SECURITY TRAINING**

a. Mandatory Training

i. All Contractor employees having access to (1) Federal information or a Federal information system or (2) sensitive data/information as defined at HHSAR 304.1300(a)(4), shall complete the NIH Computer Security Awareness Training course at http://irtsectraining.nih.gov/ before performing any work under this contract. Thereafter, Contractor employees having access to the information identified above shall complete an annual NIH-specified refresher course during the life of this contract. The Contractor shall also ensure subcontractor compliance with this training requirement.

ii. The Contractor shall maintain a listing by name and title of each Contractor/Subcontractor employee working on this contract and having access of the kind in paragraph 1.a(1) above, who has completed the NIH required training. Any additional security training completed by the Contractor/Subcontractor staff shall be included on this listing. The list shall be provided to the COTR and/or Contracting Officer upon request.

b. Role-based Training

HHS requires role-based training when responsibilities associated with a given role or position, could, upon execution, have the potential to adversely impact the security posture of one or more HHS systems. Read further guidance at Secure One HHS Memorandum on Role-Based Training Requirement.

For additional information see the following: http://ocio.nih.gov/security/security-communicating.htm#RoleBased.

The Contractor shall maintain a list of all information security training completed by each contractor/subcontractor employee working under this contract. The list shall be provided to the COTR and/or Contracting Officer upon request.

c. Rules of Behavior

The Contractor shall ensure that all employees, including subcontractor employees, comply with the NIH Information Technology General Rules of Behavior (http://ocio.nih.gov/security/nihitrob.html), which are contained in the NIH Information Security Awareness Training Course http:// irtsectraining.nih.gov.

2. **PERSONNEL SECURITY RESPONSIBILITIES**

The contractor shall comply with the below personnel security responsibilities:

a. The Contractor shall notify the Contracting officer and the COTR **within five working days** before a new employee assumes a position that requires access to HHS information systems or data, or when an employee with such access stops working on this contract. The Government will initiate a background investigation on new employees assuming a position that requires access to HHS information systems or data, and will stop pending background investigations for employees that no longer work under the contract or no longer have such access.

b. **New contractor employees who have or will have access to HHS information systems or data:** The Contractor shall provide the COTR with the name, position title, e-mail address, and phone number of all new contract employees working under the contract and provide the name, position title and position sensitivity level held by the former incumbent. If an employee is filling a new position, the Contractor shall provide a position description and the Government will determine the appropriate position sensitivity level.

c. **Departing contractor employees:** The Contractor shall provide the COTR with the name, position title, and position sensitivity level held by or pending for departing employees. The Contractor shall perform and document the actions identified in the Contractor Employee Separation Checklist (http://ocio.nih.gov/nihsecurity/Emp-sep-checklist.pdf) when a Contractor/subcontractor employee terminates work under this contract. All documentation shall be made available to the COTR upon request.

d. **Commitment to Protect Non-Public Departmental Information and Data.**

The Contractor, and any subcontractors performing under this contract, shall not release, publish, or disclose non-public Departmental information to unauthorized personnel, and shall protect such information in accordance with provisions of the following laws and any other pertinent laws and regulations governing the confidentiality of such information:

- 18 U.S.C. 641 (Criminal Code: Public Money, Property or Records)
- 18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information)
- Public Law 96-511 (Paperwork Reduction Act)

Each employee, including subcontractors, having access to non-public Department information under this acquisition shall complete the "Commitment to Protect Non-Public Information - Contractor Employee Agreement" located at: http://ocio.nih.gov/docs/public/Nondisclosure.pdf. A copy of each signed and witnessed Non-Disclosure agreement shall be submitted to the Project Officer/COTR prior to performing any work under this acquisition.

3. **Loss and/or Disclosure of Personally Identifiable Information (PII) - Notification of Data Breach**

The Contractor shall report all suspected or confirmed incidents involving the loss and/or disclosure of PII in electronic or physical form. Notification shall be made to the NIH Incident Response Team (IRT) via email (IRT@mail.nih.gov) within one hour of discovering the incident. The Contractor shall follow up with IRT by completing and submitting one of the applicable two forms below within three (3) work days of incident discovery:

NIH PII Spillage Report at: http://ocio.nih.gov/docs/public/PII_Spillage_Report.doc
NIH Lost or Stolen Assets Report at: http://ocio.nih.gov/docs/public/Lost_or_Stolen.doc

7. **ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS**

The technical proposal shall describe in detail the ability of the Principal Investigator (PI) and the Contractor to create an infrastructure consisting of multiple institutions capable of responding to requests for Letters of Intent (LOIs) and implementing successful clinical trials in a timely fashion. The ability to identify, accrue and retain the appropriate participant cohorts shall be thoroughly described. Information shall be provided which demonstrates the Contractor understands and management of important events or tasks related to clinical trials.

The discussion included in the technical proposal shall respond to the items set forth below:

I. Technical Approach and Understanding of the Project (not to exceed 40 pages)

The technical proposal shall include a Proposed Research Plan which describes the overall objectives of the project as envisaged by the Offeror, demonstrates an understanding of the needs of the Division of Cancer Prevention (DCP) and the project requirements, and outlines the overall technical approach used to achieve the objectives in the Statement of Work (SOW). The Proposed Research Plan shall address each area of the Statement of Work and describe an implementation plan demonstrating how the institution(s) will accomplish the defined work.

The Offeror shall discuss the following general issues concerning cancer preventive agent development and the conduct of prevention clinical trials:

1. The Offeror's approach to organizing resources within a single institution or utilizing multiple cooperating institutions. The Offeror shall demonstrate the ability to identify, recruit, and retain the type, number and quality of personnel required to support this clinical trial effort. The Offeror shall indicate whether the proposed research team is a new or established team and demonstrate a record of team accomplishment as it relates to cancer prevention and/or treatment research. The proposal shall include an organizational diagram that demonstrates the defined structure and lines of authority for the institution(s). Offerors are encouraged to work together and to seek collaborations within and outside their institutions in order to enhance their proposal. Since an individual institution may be awarded only one contract, investigators at institutions capable of performing studies in multiple organ sites are encouraged to work together to present a single proposal.

2. The ability of the Offeror to respond quickly to requests for LOIs, prepare protocols within a defined time line, collect and submit data as required, and ensure data quality.

3. The Offeror's approach to study design, including identification of appropriate study populations, plans for recruitment and retention of study subjects, selection of target organs and endpoints, statistical evaluation, and future application of research findings.

4. Provide evidence of the Offeror's understanding and planning for problems in study conduct and completion.

5. The Offeror's approach to a data management process including, but not limited to, data collection and quality control that ensures appropriate reporting and electronic submission of clinical trials data to DCP. See the section in the RFP on 'Reporting Requirements'.

6. The Offeror shall describe procedures, including their proposed electronic data-base, for transfer of Cancer Bioinformatics Grid (CaBIG)-compatible, patient-level, minimal data sets to DCP on a regular bases (i.e. monthly or as directed).
The Offeror's procedures for ensuring that data from correlative studies including pharmacokinetic and/or pharmacodynamic will be collected, interpreted, and reported to DCP and the community shall be described.

7. A complete discussion demonstrating the Offeror's understanding of issues related to tissue acquisition and testing, including limitations and plans that will enable achievement of study endpoints. A discussion of participant consent for use of fresh and archival tissue and ownership of tissues for research shall be included.

8. A detailed description of the Offeror's laboratory capability, including technical approach, controls, protocol standardization, data acquisition, and interpretation and description of pathology review procedures for all specimens to be used for research.

9. A detailed description of the Offeror's IRB review process, including delineation of all committee approvals required prior to IRB review both for trials performed at Offeror's institution and for trials overseen by Offeror (if awarded the contract) where accrual occurs at another institution. A plan to minimize time delay due to multiple committee reviews and IRB reviews shall be presented.

10. A description of the Offeror's quality control procedures that will be used for all imaging studies, where appropriate.

11. The Offeror's plan for coordination for multi-institutional studies (required if multi-institutional studies are proposed):
a. Methods for communication within the participating institutions (e.g., team meetings and/or conference calls).
b. Methods for collection of required documents from the participating centers including form FDA 1572, lab certifications, IRB approvals, etc.
c. Methods for central patient registration by the Contractor.
d. Methods for ensuring and maintaining appropriate accrual from participating sites.
e. Methods for timely collection and submission of accurate data from participating institutions.
f. Methods for ensuring complete collection and reporting of adverse events and serious adverse events from the participating institutions.
g. Procedures for auditing participating institutions.
h. Transport of specimens from participating institutions to reference laboratories for correlative studies.

II. Conduct of chemoprevention clinical trials (Not to exceed 50 pages)

These contracts require a level of productivity equivalent to the enrollment of 75 study participants in chemoprevention trials per year. The Technical Proposal shall provide a description of the infrastructure and organizational ability necessary to support clinical trials for this number of subjects. The page limit includes the 2 LOIs requested in section B4 below, but it does not include the budget sheets for the LOIs.

The Offeror shall:

1. Demonstrate the availability of participants for studies under the contract, plans for prioritization of contract studies with competing studies at the institution(s), and ability to complete trials in timely manner.
.
The Offeror shall either:
a. Document the accrual of at least 75 evaluable participants to IRB approved chemoprevention trials during a 12-month period within the past 5 years.

OR

b. Document access to a minimum of 500 subjects per year who could be potential candidates for the Phase 0/I/II prevention trials being proposed. Access to subjects may be demonstrated in a variety of ways, including: a) investigators' participation in high-risk clinics that follow specific genetic cohorts at risk for cancer, and 2) inclusion in the research team of appropriate subspecialists who follow subjects with premalignant conditions in various organ sites.

2. Document the completion and reporting of at least two Phase II trials and at least one Phase 1 trial (if the Offeror wishes to be considered for Phase I studies under this contract) completed at the offering institution/consortium during the past 3 to 5 years. At least one of these studies shall be a cancer prevention trial, while the other(s) may be a cancer treatment trial.

3. Provide documentation of ability to perform Phase II trials in at least 2 different target organs with documentation of clinical trials performed in those organs and/or access to populations at high risk for cancer in these 2 (or more) organ sites.

4. Provide sample LOIs for 2 different hypothetical studies in 2 different target organs (total of 2 sample studies). The LOI form provided on the DCP website (http://prevention.cancer.gov/clinicaltrials/management/consortia/step-1/protocol#loi) shall be used to present information regarding the hypothesis/rationale, subject cohort, etc. Each LOI shall be accompanied by an Implementation Plan which describes plans for staffing, cohort identification, subject recruitment and retention, compliance, and follow-up. This Implementation Plan shall also document the ability to access the appropriate physicians, subject populations, and facilities to conduct a successful chemoprevention trial. The Implementation Plan shall include estimated costs associated with the study. (Limit 10 pages total for each LOI for each proposed study). Note: LOIs previously submitted to DCP may not be used.

a. In each of the sample LOI's above, describe in detail the methodology and validation of techniques for at least 2 biomarkers analyzed by unrelated techniques.
b. For each of the LOIs above, provide a detailed budget. These budgets shall reflect the costs that will form a basis for determining the "per subject" costs for studies performed during the subsequent contract (also see the Additional Business Proposal Instructions).

5. Describe any unique features of the Offeror that will provide access to people at risk for cancer.

6. Demonstrate the resources that will allow the Offeror to maintain an acceptable accrual rate at all participating sites throughout the performance of the clinical trial.

7. Demonstrate commitment of subspecialists appropriate to the clinical care and tissue acquisition from each subject cohort (i.e., ENT surgeons, gastroenterologists, urologists, dermatologists, etc.)

8. Demonstrate the ability to promote the trial to the appropriate populations, recruit and retain subjects, coordinate communications and resources, collect and submit data accurately, and complete trials in a timely fashion.

9. Describe methods for meeting DCP deadlines for protocol related documents including the ability to prepare and submit protocols within 2 months of LOI approval, prepare and submit revised protocols within 4 weeks of receipt of Consensus Review, and promptly notifying DCP PIO of study status changes.

10. Provide evidence of adequate protection of privacy of confidential data.

III. Qualifications and Availability of Personnel Resources and Organizational Experience in Related Areas (not to exceed 30 pages, including organizational charts, but excluding resumes and letters of commitment and project summaries which can be included as Appendix material).

General:
Each area of the Statement of Work shall be addressed in sufficient detail to permit evaluation of the proposal in terms of the adequacy and availability of all staff assigned to the project. Offerors shall indicate the specific level of effort that they consider appropriate for each function outlined in the Statement of Work and indicate the approximate percentage of total time that each staff member would be available for this contract. For all proposed key personnel provide a Summary of Related

Activities describing current and outstanding funding sources and commitments and describe how the Offeror will ensure their availability when needed.

The Offeror shall provide sufficient information to indicate the hierarchical line of supervisory authority, and clearly define which contractor employee(s) will perform the various tasks.

Provide complete, detailed resumes of the Principal Investigator and all other Key personnel that indicate their educational background, recent relevant experience, and professional accomplishments shall be provided. Dates, places, and names of previous employers, and any related training shall be included. For all proposed personnel who are not currently members of the Offeror's staff, a letter of commitment is required; a resume does not meet these instructions.

Specifics:
The Contractor shall provide a personnel team with the qualifications to perform the tasks required as described in the statement of work. Examples of the types of personnel that may be required are described below:

1. Principal Investigator
The Offeror shall name a Principal Investigator who will be responsible for the overall implementation of the awarded contract and serve as the Offeror's key contact for scientific and technical aspects of the project. The Principal Investigator shall have an MD or equivalent degree and have experience in clinical investigations pertaining to early drug development. The Principal Investigator with the relevant clinical investigations experience may have a PhD, but if this is the case, then a physician with an active license shall be part of the leadership team and this medically responsible individual shall be clearly identified (see section C2 below). Experience with cancer preventive agents and in leading a team in cancer preventive agent development is highly recommended. Furthermore, the PI shall demonstrate administrative and leadership experience in recruiting and managing the organizational resources necessary to implement a successful clinical trials program. The qualifications, experience, and accomplishments of the Principal Investigator shall be discussed. The estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible shall be stated. The Principal Investigator shall be an employee of the Offeror and not a consultant or subcontractor. The Principal Investigator may serve as the Study Chair for individual protocols performed under this contract or may delegate this responsibility to a Participating Investigator. In either case, the Principal Investigator remains the individual responsible for meeting the terms and conditions of the contract.

2. Medically Responsible Investigator: If the Principal Investigator does not hold an MD or equivalent license, then a "Medically Responsible Investigator" with responsibility for medical oversight of all of the Offeror's clinical trials shall be designated. The Medically Responsible Investigator shall be a physician with an MD degree or equivalent and shall hold an active license. The Medically Responsible Investigator shall be familiar with the guidelines of Good Clinical Practice, have experience in early phase drug development and clinical trials, and shall be an employee of the Offeror and not a consultant or subcontractor.

3. Participating Investigators: Participating Investigators may participate in one or more protocols performed under this contract and may serve as the Study Chairs for protocols awarded under this contract. Participating Investigators may be from either the Offeror's institution or from a Participating Organization. Participating Investigators may be physicians with the MD degree or equivalent with past experience in clinical trials. Participating Investigators shall be familiar with the guidelines of Good Clinical Practice and shall demonstrate the availability and commitment to accrue subjects to chemoprevention trials. Appropriate medical and surgical specialties shall be represented to

ensure access to and the appropriate care of the targeted high-risk populations; these Participating Investigators shall demonstrate understanding of the disease process relevant to the chosen organ sites.

4. Team Experience
Individuals on the team shall have aggregate experience in the following areas:

a. Cancer prevention drug development

b. Phase I (if appropriate) and II clinical trials experience, preferably with populations at high risk for cancer. Recruitment, assessment of eligibility, consent, and clinical evaluation of subjects receiving investigational agents shall be addressed. Ability to perform pharmacokinetic studies for Phase I trials shall be documented if proposing to perform such studies for this contract.

c. Ability to collect, edit and transmit patient level clinical and administrative data

d. Statistical analysis: capability of choosing and executing statistical techniques for the design and analysis of Phase I and II studies and to correlate laboratory parameters with treatment outcome.

e. Cancer biomarker studies: 1) ability to obtain and process blood and other tissues for research purposes from subjects in clinical trials, 2) ability to perform innovative translational studies and to correlate these data with the administered treatment, 3) ability to perform pharmacokinetic and/or pharmacodynamic studies, 4) participation of appropriate subspecialties to obtain tissue for these studies (e.g., gastroenterologists, bronchoscopists, urologists, etc.), 5) appropriate pathology and lab medicine support, and 6) use of innovative imaging technologies where appropriate.

Offerors need to provide evidence of their own expertise, or access to medical or surgical specialties appropriate to the organ sites under study.

f. Availability of investigational imaging personnel resources, if appropriate.

g. Evidence of productivity in completion of trials and relevant biomarker evaluations.
i. The Offeror shall document the team's experience in completing and reporting Phase I (if applicable) and Phase II cancer prevention and/or treatment trials. This includes presentation at meetings and publication of results in peer-reviewed publications.
ii. The proposal shall include a table to demonstrate evidence of the team's productivity in completion of trials and relevant biomarker evaluations. The table shall include the following data representing ongoing and completed trials conducted over the past 3-5 years:
Name of trial
Protocol number
Cohort and target organ studies
Agent
Subject accrual: total number accrued (expected and actual), start and end date of accrual
Study sponsor (i.e., NCI, pharmaceutical company, etc.)
Publication references
Offeror's role in trial (PI, Study Chair, Participating Investigator, etc.)

4. Pertinent Organizational Experience in Related Areas (Note the page limitations for this section exclude specific documentation of each prior project; i.e., do not include project summaries).

a. For proposals involving multiple institutions, the Offeror shall clearly document their past experience in leading and/or participating in multi-institutional trials. The recommended experience may include participation in any multi-institutional trial, including, but not limited to, cooperative group trials or multi-center pharmaceutical company trials. For each proposed member institution, document the trials conducted, and each member's accrual contribution. For Offeror's with existing multi-institution experience, describe the structure, organization and coordination of such collaborations. For Offerors without existing multiple institution experience, describe the plans for rapidly structuring and initiating the collaboration(s).

b. Specifically describe institutional processes for departmental and other committee reviews as well as the IRB process, providing timelines for the review of newly submitted protocols. Address how multiple concurrent or sequential reviews within a proposed multi-institutional consortium will be handled and how delays to protocol approval and activation will be minimized.

IV. Facilities and Equipment (not to exceed 5 pages)

1. The Offeror shall include detailed information regarding the facilities, equipment, location and available space for use on this project, and clearly describe how they will be available at the start of the project. The Offeror shall give all particulars regarding the facilities for clinical studies including:

a. Clinical facilities shall be described in detail. Describe staff/space available for observation of study subjects.

b. Investigational Agent Pharmacy - the Offeror shall provide information detailing adequate pharmacy staff and facilities to ensure the secure storage and accountability of DCP-supplied investigational agents. This shall include adequate equipment to ensure the integrity and secure storage of agents requiring storage at sustained temperatures of room temperature, 4o C, -20o C, and -70o C.

c. Pathology and Correlative Studies- Describe resources available such as automatic staining equipment, microdissection, molecular technologies.

d. Imaging (where applicable) - Imaging facilities shall be described in detail with emphasis on technologies available for imaging at the molecular and cellular level. Also describe facilities available for image guided procedures such as tissue biopsy, if relevant.

2. The Offeror shall have e-mail and Internet capabilities and have the capability (or demonstrate how it will acquire the capability) to submit data electronically to NCI. The Offeror shall have the ability to attach, send and receive documents (for example, protocols, amendments, correspondence) via e-mail.

V. Other Considerations (not to exceed 5 pages)

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

1. Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.

2. Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.

3. Other factors you feel are important and support your proposed research.

VI. List of Government Furnished Information/Reference Materials

http://prevention.cancer.gov/clinicaltrials/management/consortia
http://prevention.cancer.gov/clinicaltrials/management/consortia/step-1/protocol
http://prevention.cancer.gov/clinicaltrials/management/consortia/step-1/protocol#loi
http://prevention.cancer.gov/clinicaltrials/management/consortia/step-1/multi
http://prevention.cancer.gov/clinicaltrials/management/consortia/step-1/agent
http://www.hhs.gov/ohrp/policy/index.html#human
http://www.cancer.gov/clinicaltrials/conducting/dsm-guidelines
http://prevention.cancer.gov/clinicaltrials/management/pio/instructions
http://ctep.cancer.gov/protocolDevelopment/electronic_applications/ctc.htm#ctc_40

http://oma.od.nih.gov/ms/records/

c. **BUSINESS PROPOSAL INSTRUCTIONS**

1. **Basic Cost/Price Information**

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

2. **Proposal Cover Sheet**

The following information shall be provided on the first page of your pricing proposal:

1. Solicitation, contract, and/or modification number;
2. Name and address of Offeror;
3. Name and telephone number of point of contact;
4. Name, address, and telephone number of Contract Administration Office, (if available);
5. Name, address, and telephone number of Audit Office (if available);
6. Proposed cost and/or price; profit or fee (as applicable); and total;
7. The following statement: By submitting this proposal, the offeror, if selected for discussions, grants the contracting officer or an authorized representative the right to examine, at any time before award, any of those books, records, documents, or other records directly pertinent to the information requested or submitted.

8. Date of submission; and

9. Name, title and signature of authorized representative.

   This cover sheet information is for use by offerors to submit information to the Government when certified cost or pricing data are not required but information to help establish price reasonableness or cost realism is necessary. Such information is not required to be certified in accordance with FAR 15.406-2.

3. **Data Other than Certified Cost or Pricing Data**

   a. Data submitted shall be sufficient to permit the Contracting Officer and authorized representatives to determine price reasonableness or cost realism, e.g., data to support an analysis of material costs (when sufficient data on labor and overhead rates is already available), or data on prices and quantities at which the offeror has previously sold the same or similar items.

      Data submitted must support the price proposed. The offeror shall include sufficient detail or cross references to clearly establish the relationship of the data provided to the price proposed. The offeror shall support any data provided with explanations or supporting rationale, as needed, to permit the Contracting Officer and authorized representative to evaluate the documentation.

      [Unless otherwise stated in this solicitation, the information may be submitted in the offeror's own format.]

   b. The data submitted shall be at the level of detail described below.

      a. **Direct Labor**

         Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category. Key personnel will be separately estimated as above and identified. Give the basis for the estimates in each case.

      b. **Materials**

         Provide a consolidated price summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.).

      c. **Subcontracted Items**

         Include parts, components, assemblies, and services that are to be produced or performed by others in accordance with offeror's design, specifications, or direction and that are applicable only to the prime contract. For each subcontract over $650,000, the support should provide a listing by source, item, quantity, price, type of subcontract, degree of competition, and basis for establishing source and reasonableness of price, as well as the results of review and evaluation of subcontract proposals when required by FAR 15.404-3.

      d. **Raw Materials**

         Consists of material in a form or state that requires further processing. Provide priced quantities of items required for the proposal.

      e. **Purchased Parts**

Includes material items not covered above. Provide priced quantities of items required for the proposal.

f. **Fringe Benefits**

Show fringe benefits as a separate line item. Include the rate(s) and/or method of calculating fringe benefits. Provide a copy of your fringe benefit rate or institutional guidelines.

g. **Indirect Costs**

Indicate how offeror has computed and applied offeror's indirect costs, including cost breakdowns, and provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation. Where a rate agreement exists, provide a copy.

h. **Special Equipment**

If direct charge, list any equipment in accordance with Item (13) Other Administrative Data, subparagraph (2) Government Property of this Section L.2.c of this solicitation.

i. **Travel**

Provide the cost of travel including destination, duration, purpose, per diem, transportation, and the basis for pricing.

j. **Other Costs**

List all other costs not otherwise included in the categories described above (e.g., computer services, consultant services) and provide basis for pricing.

4. **Requirements for Certified Cost or Pricing Data and Data Other than Certified Cost or Pricing Data, FAR Clause 52.215-20** (October 2010)

(a) Exceptions from certified cost or pricing data.

(1) In lieu of submitting certified cost or pricing data, offerors may submit a written request for exception by submitting the information described in the following subparagraphs. The Contracting Officer may require additional supporting information, but only to the extent necessary to determine whether an exception should be granted, and whether the price is fair and reasonable.

(i) Identification of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.
(ii) Commercial item exception. For a commercial item exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include

(A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;

(B) For market priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;
(C) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item.

(2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and the reasonableness of price. For items priced using catalog or market prices, or law or regulation, access does not extend to cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace.

(b) Requirements for certified cost or pricing data. If the offeror is not granted an exception from the requirement to submit certified cost or pricing data, the following applies:

(1) The offeror shall prepare and submit certified cost or pricing data, data other than certified cost or pricing data, and supporting attachments in accordance with the instructions contained in Table 15-2 of FAR 15.408, which is incorporated by reference with the same force and effect as though it were inserted here in full text. The instructions in Table 15-2 are incorporated as a mandatory format to be used in this contract, unless the Contracting Officer and the Contractor agree to a different format and change this clause to use Alternate I.
(2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406-2.

(End of provision)

5. **Salary Rate Limitation in Fiscal Year 2011**

Offerors are advised that pursuant to P.L. **, no NIH Fiscal Year 2011 (October 1, 2010 - September 30, 2011) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level I* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the Contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the Contractor.

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level I*. The salary rate limitation set by P.L. ** applies only to Fiscal Year 2011 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I* annual salary rate limitation also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. ** states in pertinent part:

"None of the funds appropriated in this Act for the National Institutes of Health, the Agency for Healthcare Research and Quality, and the Substance Abuse, and Mental Health Services Administration shall be used to pay the salary of an individual through a grant or other extramural mechanism at a rate in excess of Executive Level I*."

LINK TO EXECUTIVE SCHEDULE SALARIES: http://www.opm.gov/oca/10tables/indexSES.asp

***Note to Offerors**: The current Fiscal Year Executive Level I Salary Rate shall be adhered to in the preparation of your proposal. All costs associated with any resultant contract award shall be in compliance with the current Fiscal Year Executive Level I Salary rates.

**Pending passage of legislation.

6. **Small Business Subcontracting Plan**

If the proposed contract exceeds a total estimated cost of $650,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation, See SECTION J - LIST OF ATTACHMENTS, BUSINESS PROPOSAL ATTACHMENTS of this RFP for an example of such a plan.

a. THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.

b. The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.

c. The offeror understands that:

1. No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.

2. An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HUBZone Small Businesses, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.

3. If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.

4. Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.

5. It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HUBZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the offeror's plan will be judged independent of the other.

6. The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.

d. Each plan must contain the following:

1. Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors.
2. A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.
3. A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned and/or Service Disabled Veteran-Owned Small Business Concerns.
4. A description of the method used to develop the subcontracting goals.
5. A description of the method used to identify potential sources for solicitation purposes.
6. A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.
7. The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.
8. A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.
9. Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of $650,000 adopt a plan similar to the plan agreed upon by the offeror.
10. Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (Individual Subcontract Reports (ISRs) and Summary Subcontract Reports (SSRs) to the Government.
11. List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

    For additional information about each of the above elements required to be contained in the subcontracting plan, see FAR Clause 52.219-9, Small Business Subcontracting Plan, and the Sample Subcontracting Plan which is provided as an attachment to this RFP in SECTION J.

    HHS expects each procuring activity to establish minimum subcontracting goals for all procurements. The anticipated minimum goals for this RFP are as follows:

    39.9% for Small Business; 5% for Small Disadvantaged Business; 5% for Women-Owned Small Business; 3% for HUBZone Small Business; and 3% for Veteran-Owned Small Business and Service-Disabled Veteran-Owned Small Business.

7. **Mentor-Protégé Program, HHSAR 352.219-70 (January 2010)**

a. Large business prime contractors serving as mentors in the HHS Mentor-Protégé program are eligible for HHS subcontracting plan credit, and shall submit a copy of their HHS Office of Small and Disadvantaged Business Utilization (OSDBU)-approved mentor protégé agreements as part of their offers. The amount of credit provided by the Contracting Officer to a mentor firm for protégé firm developmental assistance costs shall be calculated on a dollar for dollar basis and reported by the mentor firm in the Summary Subcontract Report via the Electronic Subcontracting Reporting System (eSRS) at http://www.esrs.gov. The mentor firm and protégé firm shall submit to the Contracting Officer a signed joint statement agreeing on the dollar value of the developmental assistance the mentor firm provided. (For example, a mentor firm would report a $10,000 subcontract awarded to a protégé firm and provision of $5,000 of developmental assistance as $15,000 of developmental assistance.) The mentor firm may use this additional credit towards attaining its subcontracting plan participation goal under this contract.

b. The program consists of--

i. Mentor firms--large businesses that: (i) demonstrate the interest, commitment, and capability to provide developmental assistance to small business protégé firms; and (ii) have a Mentor-Protégé agreement approved by HHS' OSDBU;

ii. Protégé firms--firms that: (i) seek developmental assistance; (ii) qualify as small businesses, veteran-owned small businesses, service-disabled veteran-owned small businesses, HUBZone small businesses, small disadvantaged businesses, or woman-owned businesses; and (iii) have a Mentor-Protégé agreement approved by HHS' OSDBU; and

iii. Mentor-Protégé agreements--joint agreements, approved by HHS' OSDBU, which detail the specific terms, conditions, and responsibilities of the mentor-protégé relationship.

(End of provision)

8. **HUBZone Small Business Concerns**

Small Business offerors located in underutilized business zones, called "HUBZones," will be evaluated in accordance with FAR Clause 52.219-4, NOTICE OF PRICE EVALUATION PREFERENCE FOR HUBZONE SMALL BUSINESS CONCERNS, which is incorporated by reference in ARTICLE I.3. of this solicitation. Qualified HUBZone firms are identified in the Small Business Administration website at http://www.sba.gov/hubzone.

9. **Extent of Small Disadvantaged Business Participation**

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Industry Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed $650,000 ($1.5 million for construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

The factor entitled "Extent of Small Disadvantaged Business Participation" as set forth in Section M - Evaluation Factors for Award shall be used for evaluation purposes.

The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) codes, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). The NAICS codes can be found at: http://www.sba.gov/size

The Department of Commerce website for the annual determination for NAICS codes* is:

http://www.acquisition.gov/References/sdbadjustments.htm.

** Note: Public Law 103-355 which authorized the SDB Price Evaluation Adjustment (PEA) and associated percentages/factors expired on December 9, 2004, therefore, the percentages shown at this website are no longer applicable.*

Offerors shall include with their offers, SDB targets, expressed as dollars and percentages of total contract value, in each of the applicable, authorized NAICS Industry Subsector(s). The applicable authorized NAICS Industry Subsector(s) for this project is (are) identified elsewhere in this RFP.

A total target for SDB participation by the Prime Contractor, that includes any joint ventures and team members, shall be provided as well as a total target for SDB participation by subcontractors. In addition, offerors must provide information that describes their plans for meeting the targets set forth in their proposal. **This information shall be provided in one clearly marked section of the Business Proposal, which shall describe the extent of participation of SDB concerns in the performance of the contract.**

If the evaluation factor in this solicitation includes an SDB evaluation factor or subfactor that considers the extent to which SDB concerns are specifically identified, the SDB concerns considered in the evaluation shall be listed in any resultant contract. Offerors should note that addressing the extent of small disadvantaged business participation **is not in any way intended to be a substitute** for submission of the subcontracting plan, if it is required by this solicitation. An example of the type of information that might be given (in addition to the narrative describing the plan for meeting the targets) follows:

EXAMPLE

Targets for SDB Participation - NAICS Industry Subsector 223

	SDB Percentage of Total Contract Value	**SDB Dollars**
Total Contract Value- $1,000,000	25%	$250,000
SDB Participation by Prime	10%	$100,000
(Includes joint venture partners and team arrangements)*		
SDB Participation by subcontractors	15%	$150,000

*Note: FAR Subpart 9.6 defines "Contractor team arrangements" to include two or more companies forming a partnership or joint venture to act as a potential Prime Contractor, or a potential Prime Contractor who agrees with one or more companies to have them act as its subcontractors on a specific contract or acquisition program. For purposes of evaluation of the SDB participation factor, FAR 19.1202-4 requires that SDB joint ventures and teaming arrangements at the prime level be presented separately from SDB participation by subcontractors.

10. **Total Compensation Plan**

    a. **Instructions**

1. Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by recompetition of these contracts. Lowering of compensation can be detrimental in obtaining the necessary quality of professional services needed for adequate performance of service contracts. It is, therefore, in the best interest of the Government that professional employees, as defined in 29 CFR Part 541, be properly compensated in these contracts. All offerors as a part of their Business Proposal will submit a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes.

2. The Government will evaluate the Total Compensation Plan to ensure that this compensation reflects a sound management approach and an understanding of the requirements to be performed. It will include an assessment of the offeror's ability to provide uninterrupted work of high quality. The total compensation proposed will be evaluated in terms of enhancing recruitment and retention of personnel and its realism and consistency with a total plan for compensation (both salaries and fringe benefits).

3. Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror.

b. **Evaluation**

1. **Total Compensation Plan (Professional Employees)**

   In establishing compensation levels for professional employees, the total compensation (both salaries and fringe benefits) proposed shall reflect a clear understanding of the requirements of the work to be accomplished and the suitability of the proposed compensation structure to obtain and retain qualified personnel to meet mission objectives. The salary rates or ranges must recognize the distinct differences in professional skills and the complexity of varied disciplines as well as job difficulty. Proposals offering total compensation levels less than currently being paid by the predecessor Contractor for the same work will be evaluated, in addition to the above, on the basis of maintaining program continuity, uninterrupted work of high quality, and availability of required competent professional employees. Offerors are cautioned that instances of lowered compensation for essentially the same professional work may be considered a lack of sound management judgment in addition to indicating a lack of understanding of the requirement.

2. **Cost (Professional Compensation)**

   Proposals which are unrealistically low or do not reflect a reasonable relationship of compensation to the professional job categories so as to impair the Contractor's ability to recruit and retain competent professional employees, may be viewed as reflecting a failure to comprehend the complexity of the contract requirements. The Government is concerned with the quality and stability of the work force to be employed on this contract. The compensation data required will be used in evaluation of the offeror's understanding of the contract requirements.

3. **Other (Labor Relations)**

   An assessment of the potential for adverse effect upon performance and maintenance of the required number of professional employees with requisite skills resulting from an unrealistically low compensation structure will also be made.

4. **Federal Acquisition Regulation Clauses incorporated by Reference**

   FAR Clause 52.222-46, Evaluation of Compensation for Professional Employees (FEBRUARY 1993).

11. **Other Administrative Data**

a. **Property**

1. It is HHS policy that Contractors will provide all property necessary for contract performance. Exception may be granted to provide Government property (Government-furnished or Contractor-acquired), but only when approved by the Contracting Officer. If the offeror requests that Government property be provided, other than that specified under "Government Furnished Property," below , the proposal must include a comprehensive justification addressing the following items:

    a. State why the property is essential to contract performance and whether the property will be used exclusively for this contract.

    b. Describe other alternatives (e.g., purchase, lease, etc.) pursued and why they were not viable options.

2. Government Property

    The offeror shall identify Government property in its possession which it proposes to use in the performance of the prospective contract as follows:

    a. A list or description of all Government property that the offeror or its subcontractors propose to use on a rent-free basis. The list shall identify the accountable contract under which the property is held and the authorization for its use (from the Contracting Officer having cognizance of the property);

    b. The dates during which the property will be available for use (including the first, last, and all intervening months) and, for any property that will be used concurrently in performing two or more contracts, the amounts of the respective uses in sufficient detail to support prorating the rent;

    c. The amount of rent that would otherwise be charged in accordance with FAR 52.245-9, Use and Charges; and

    d. The voluntary consensus standard or industry leading practices and standards to be used in the management of Government property, or existing property management plans, methods, practices, or procedures for accounting for property.

    NOTE: The Contracting Officer will consider any potentially unfair competitive advantage that may result from the Contractor possessing Government property, and for evaluation purposes only, adjust the offers using a rental equivalent evaluation factor, as appropriate.

3. Government-Furnished Property

    No Government Furnished Property is offered for this acquisition

4. The management and control of any Government property shall be in accordance with the HHS Publication entitled, "HHS Contracting Guide for Contract of Government Property," which can be found at: http://rcb.cancer.gov/rcb-internet/reference/Appendix Q_HHS Contracting Guide.pdf

b. ***Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38*** *(MAY 1999)*

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232 34, Payment by Electronic Funds Transfer Other than Central Contractor Registration.

(1) The solicitation number (or other procurement identification number).
(2) The offeror's name and remittance address, as stated in the offer.
(3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
(4) The name, address, and 9 digit Routing Transit Number of the offeror's financial agent.
(5) The offeror's account number and the type of account (checking, savings, or lockbox).
(6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.
(7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9 digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

(End of Provision)

c. **Financial Capacity**

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

d. **Incremental Funding**

An incrementally funded contract is a contract in which funds are obligated, as they become available, to cover specific periods of performance.

Incremental Funding, HHSAR 352.232-70 (June 2010)

The Government intends to negotiate and award a cost-reimbursement contract using incremental funding as described in the clauses at FAR 52.232-22, "Limitation of Funds," and 352.232-71, "Estimated Cost - Incrementally Funded Contract." The initial obligation of funds under the contract is expected to cover _____ . The Government intends to obligate additional funds up to and including the full estimated cost of the contract for the remaining years of performance by unilateral contract modification. However, the Government is not required to reimburse the Contractor for costs incurred in excess of the total amount obligated, nor is the Contractor required to perform beyond the level supported by the total amount obligated.

(End of provision)

12. **Qualifications of the Offeror**

You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

a. **General Experience**

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

b. **Organizational Experience Related to the RFP**

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

c. **Performance History**

Performance history is defined as meeting contract objectives within **delivery** and **cost schedules** on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

d. **Pertinent Contracts**

Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

e. **Pertinent Grants**

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

13. **Subcontractors**

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

a. Willingness to perform as a subcontractor for specific duties (list duties).

b. What priority the work will be given and how it will relate to other work.

c. The amount of time and facilities available to this project.

d. Information on their cognizant field audit offices.

e. How rights to publications and patents are to be handled.

f. A complete cost proposal in the same format as the offeror's cost proposal.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:

http://ocm.od.nih.gov/contracts/rfps/FDP/FDPclausecover.htm

14. **Proposer's Annual Financial Report**

A copy of the organization's most recent annual report must be submitted as part of the business proposal.

15. **Travel Costs/Travel Policy**

a. **Travel Policy**
One copy of the offeror's (and any proposed subcontractor's) written travel policy shall be included in the business proposal (original only). If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

16. **Additional Business Proposal Instructions**

Information to Assist Offerors in Cost Proposal Preparation

The Government includes the following information for proposal preparation purposes only.

a. The Government is planning to award 5-6 contracts for a base period of five years. However, to cover the costs of clinical trials that are begun in the last 2 years of the contract, options to cover 'core costs' for an additional 2 years (option years 1 and 2) will be negotiated. In addition, options to accrue additional study participants, above the number specified in the base contract, will be negotiated for years 2-5 of the contracts (see section A. 1. b. ii, Additional Per Subject Options on p.6 of this document).

For purposes of responding to this RFP, the Offeror shall describe the methodology used to determine the proposed Core Costs, Per Subject Costs, Per Protocol Costs (provide two sample Letter of Intent (LOI) budgets as described in the Additional Technical Proposal Instructions). A template is provided for calculation of the overall budget.

b. Method of Reimbursement for Accrual

Payment under this contract shall be cost reimbursable and include three categories: i) Core Costs; ii) Per Subject Costs; and iii) Per Protocol Costs. These areas are defined as follows:

i. CORE COSTS

Core costs are those costs which are necessary for the performance of this contract separate from subject accrual activities and analysis of specimens. The purpose of these funds is to create and support the infrastructure that will enable the rapid performance of clinical trials. The Core costs will reflect only those costs necessary for the overall direction and administrative management of the contract.

Core costs shall include:
• Effort for the overall direction and administrative management of the project (Principal Investigator, Site Coordinator for the contract)
• Scientific development and document preparation including Letters of Intent (LOIs), Contract Work Assignments (W.A.), protocols, case report forms, response to Consensus review, protocol amendments, etc.
• Report preparation including: protocol progress reports, annual contract reports, manuscript preparation, etc.
• Data management

• Monitoring costs (personnel and travel) for overseeing the activities of participating sites. One monitoring visit per year for 3 days each (inclusive of travel) at each accruing site by one staff person.

For budget preparation purposes, Offerors should assume 6 participating sites will be actively accruing at any given time (since some studies will be multi-institutional, but some of the studies are expected to take place at the Offeror's institution and some sites may be performing more than one clinical trial). Thus in years 3-5, 6 monitoring visits will be expected to occur, with costs based on sites that the Offerors propose to include in their consortia. In year 2, when accrual is expected to commence, 2 monitoring visits should be assumed. In the option years, four monitoring visits are anticipated each year.

	Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7
# monitoring visits	0	2	6	6	6	4	4

• Investigator travel for purposes of the proposal assume two meetings per year for the PI to attend DCP Early Phase Clinical Trials Executive Committee and Agent Development Meetings (one will be held at the NCI in Bethesda, MD, while the other one will be timed to coincide with a major cancer meeting such as the annual AACR meeting or the AACR Frontiers in Cancer Prevention Meeting and will be held there). Offerors should assume that travel will last for 3 days each time.
• Travel for Core Site Coordinator - One meeting per year for three days (inclusive of travel) for the contract Core Site Coordinator to attend the 'Site Coordinators Opportunity for Research Excellence' (SCORE) meeting in Bethesda, Maryland.
• Travel for up to three Protocol Site Coordinators per year, across all active protocols, to attend SCORE in Bethesda, MD (3 days inclusive of travel).
• Materials and Supplies
• Teleconferencing

Since 'core costs' are needed to provide support to clinical trials that may still be ongoing after the 5 base years of the contract, options for 2 additional years of 'core costs' should be proposed by the Offeror.

ii. PER SUBJECT COSTS

Per Subject Costs are those common costs incurred as subjects are accrued. These costs include all costs associated with the accrual and treatment of subjects on study, as indicated below. A base per subject rate will be applied to all evaluable subjects at all participating sites for each protocol. A "Complexity Model" will be used to allow for reimbursement of more complicated studies requiring greater staff and laboratory resources (see below). For example, for more complex studies, multiples of the 'per subject' rates (up to 3x the negotiated rate, in increments of 0.5) may be requested and negotiated at the time of LOI submission. These negotiated rates will be used to determine a Per Subject cost for that protocol. The full details for calculating the "Complexity Model" are provided below.

Costs to be included in the 'Per Subject' category shall include:
• Effort for the investigator(s) leading the clinical trial(s) (except for a single overall study PI, whose effort will be included in the 'Per Protocol' costs, as outlined below in section iii).
• Nurses, Clinical Research Associates (CRAs) and data managers to accomplish subject recruitment, obtain informed consent, register subjects, manage data, treatment, follow-up (except for a single overall study site coordinator, whose effort will be included in the 'Per Protocol' costs, as outlined below in section iii).
• Patient care costs that are not covered by insurance, including office visits, general laboratory evaluations, pharmacy fees for defined studies, invasive procedures (see below Complexity Model), IRB fees, etc.
• Costs that are not covered by insurance will be reimbursed at Medicare allowable rates.

Complexity Model - Because the complexity of cancer prevention clinical trials varies and invasive screening to identify the appropriate high-risk cohort is frequently required, the Offeror shall use the Complexity Model Table 1 - Subject Costs below as a framework for determining 'per subject' costs. Prior to entering the intervention phase of a study, a subject will undergo screening to determine eligibility. The screening may be simple, such as via history and standard blood tests, or it may also require invasive biopsies. Not all screened subjects will be eligible to proceed to the intervention phase of the trial. The Complexity Model allows for reimbursement for invasive screening of subjects who do not turn out to be eligible. Table 1 below demonstrates this Model.

Complexity Model Table 1 - Subject Costs

Stage	Base Cost	x 1.5	x 2.0	x 2.5	x 3.0
Screening 1	$ x	$ 1.5x	$ 2x	$ 2.5x	$ 3x
Screening 2	$ y	$ 1.5y	$ 2y	$ 2.5y	$ 3y
Intervention	$ z	$ 1.5z	$ 2z	$ 2.5z	$ 3z

It should be assumed that the base 'per subject' cost would be the amount that would cover all subject accrual costs for one participant in a one month trial with blood- or urine-based biomarker endpoints, such as pharmacokinetics (in other words, with endpoints obtained via non-invasive means). 'Per subject' costs typically included in such a study would include 2 or 3 subject visits with history, physical exams, standard laboratory analyses, and experimental blood or urine collections. For a more complicated 6 month Phase IIb trial requiring 2 endoscopic procedures and 6 subject visits with physical exams and bloodwork at each visit, a reimbursement rate of 2.0-3.0x the base 'per subject' cost may be more appropriate and will be negotiated at the time of LOI submission (as noted above).

For purposes of the proposal, the Offeror shall propose base costs for various levels of screening ranging from most basic (non-invasive procedures, 'Screening 1' base cost) to complex (invasive endoscopic procedures with multiple biopsies, 'Screening 2' base cost). For instance, the initial base screening could consist of a simple blood test such as a basic metabolic panel (this would become the 'Screening 1' stratum base cost). If eligibility for a particular protocol required several blood tests, it might be considered 'Screening 1' base cost times 2. The 'Screening 2' stratum would be applicable to more expensive tests such as biopsies, with the base cost for Screening 2 being a straightforward, one-time biopsy of the skin, for instance, and increasing costs in the 'Screening 2' stratum being applicable to more complicated endoscopic procedures such as bronchoscopies. In the 'Intervention' stratum, the costs for the intervention portion of the study would be included. So, the cost of a simple one month intervention with 2 or 3 physician visits would be the base cost for the 'Intervention' stratum, while a complicated 6 month study with 6 physician visits and multiple safety blood checks may be 2 or 3 times the base cost for the 'Intervention'. Of note, the 'per subject' costs for a given study would consist of the sum of the 'Screening 1' and/or 'Screening 2' and 'Intervention' costs.

For purposes of the trials, not all studies will have both 'Screening 1' and 'Screening 2' costs. The complexity of 'Screening 1', 'Screening 2', and 'Intervention' need not be the same. For instance, a study could require 'Screening 1' to be at the base cost, have no 'Screening 2' cost, but require 'Intervention' costs to be two times the base cost. Finally, for a given study, the number of screens in the 'Screening 1' or 'Screening 2' stratum may be considerably greater than in the 'Intervention' stratum, if a specific profile is required for eligibility. The number of subjects in the intervention stratum will ultimately total the completed subjects for the entire contract period. The study complexity (the number of 'Screening 1', 'Screening 2', and 'Intervention'' costs) will have to be worked out for each study, within the LOI and during protocol negotiations.

An example of how this schema would work in determining the costs for a proposed LOI is as follows: For a bronchial dysplasia study, 1000 smokers may require screening with sputum ('Screening 1', perhaps at the base cost), 500 of these smokers may go on to bronchoscopy ('Screening 2', at 2x the base), and 100 subjects with dysplasia will ultimately go on to treatment ('Intervention'', at 2x

the base). The total estimated cost would equal the sum of 1,000 'Screening 1' base costs, 500 'Screening 2' base costs times 2, and 100 'Intervention" base costs times 2 [the total would be the sum of 1,000 Screening 1 costs of (x) plus 500 Screening 2 costs of (2y) plus 100 Intervention costs of (2z)]. At the time of each LOI proposal submission, the Contractor shall propose the 'per subject' costs for the trial, broken down into the 'Screening 1', 'Screening 2', and 'Intervention' strata, along with a justification for each.

As a subject is accrued to protocol studies under this contract (i.e., the subject has met requirements for intervention and is entered onto the treatment part of the trial), the Contractor may charge the billing rate for that subject during the applicable period under which the subject was accrued. If a subject comes off the study early, until the halfway point of the planned intervention period, then half the negotiated per subject rate will be billed and reimbursed. If the subject comes off the study after the halfway point of the planned intervention period, then the entire per subject rate will be billed and reimbursed.

For Budget Preparation Purposes Only - It is expected that 75 intervention subjects/year will be accrued across all studies in the contract, beginning with year 2 of the contract. The Offeror should assume that 2 new studies will begin in year 2, with 1-2 new studies beginning each year in years 3-5, for a total of 6 new studies over the five years of the contract (75 intervention subjects will be accrued per year across all the studies, for a total of 300 intervention subjects over 4 years - the first year is for LOI preparation/negotiation and the option years will be to complete studies already started). Of the potential 6 studies over the life of the contract, 3 studies should be proposed at low complexity Phase 0, Phase I, or simple biomarker trials; two studies should be proposed of moderate complexity; and one study should be proposed as a high complexity Phase IIb trial. Budgeting for 'per subject' costs for the entire contract should be based on the total of 300 subjects undergoing interventions (75 subjects/yr x 4 years).

Offerors should provide in their proposal a completed Complexity Model Table 1 based on the above model of studies. It is assumed that costs will go up by 2% per year for all Per Subject Costs. The Complexity Model Table 1 below should be revised each year for the 2% escalation. In addition, provide a companion chart entitled Complexity Model Table 2 (see below) indicating the estimated number of subjects per complexity level for the 6 studies budgeted, remembering that the intervention number should not exceed 300 total intervention subjects.

Complexity Model Table 2 - Subject Numbers

Stage	Base	x 1.5	x 2.0	x 2.5	x 3.0
Screening 1	x	x	x	x	x
Screening 2	x	x	x	x	x
Intervention	x	x	x	x	x

Additional Per Subject Options
Options for accrual of 50 additional subjects over the period of this contract (12 per year in years 2 and 3; 13 per year in years 4 and 5) shall be proposed, using the same assumptions for budgeting of 'per subject' and 'per protocol' costs as for the base contract.

iii. PER PROTOCOL COSTS

The 'Per Protocol' costs will be limited to supporting the direct costs of each clinical protocol.

Per Protocol Costs include and are limited to:
• Protocol PI salary [not to exceed 10% Level of Effort (LOE) for the first year of the study and 5% LOE for subsequent years]
• Site coordinator salary (not to exceed 50% LOE)
• Materials & Supplies
• Biospecimen shipping and storage costs
• Advertising for protocol subjects
• Biomarker/Laboratory Studies - See description below

The Biomarker-Laboratory Studies will assess biomarker endpoints performed on subject-derived specimens. All biomarkers are to be priced on a per specimen, per test basis. Additional salary costs for laboratory-based PIs will not be reimbursed within this cost element. Typical assays used in clinical trials, such as immunohistochemistry, pharmacokinetic analyses, RT-PCR (reverse transcription polymerase chain reaction), gene expression analysis via microarrays, special imaging modalities, and others may be used to assess biomarker endpoints.

For Budget Preparation Purposes: Offerors should use the model of studies provided in the 'per subject' costs in section "ii" above (300 subjects, 6 studies of varying complexity as outlined above) to determine the 'Per Protocol' costs. Offerors should assume in their budgets that 5 biomarker endpoints are generally assessed for each participant accrued to a cancer prevention clinical trial.

II. **Subcontracts**

It is expected that Contractors will subcontract with multiple participating sites to speed study performance and accrual. The execution of subcontracts is frequently a lengthy process that can delay study opening. The Offerors shall provide information regarding their institutional Standard Operating Procedures for execution of subcontracts and also their plan to optimize subcontract execution, minimizing delays to the extent possible. Whenever possible, letters of commitment from proposed subcontracting organizations should be included in the proposal.

III. **Uniform Assumptions**
Core Cost FTE estimations: To assist Offerors in the preparation of their proposals, the Government considers the effort to be a total of 21 FTEs over five years for Core costs. It is estimated that over the 2 option years a total of 7 FTEs will be required for the Core costs. The Government estimate is based on the assumption that the following types of personnel will be needed: Consortia PI, Consortia Site Coordinator, Consortia Program Manager, Data Manager, Statistician, Statistical Analyst, Protocol Specialist/Assistant, Programmer, and Study Monitor. One person may provide several roles and not all roles may need to be filled each year.

Per Protocol Cost FTE estimations: As outlined above in the 'per protocol costs' (section A.1.iii), partial salary support will be provided for the main PI for each study (one per protocol) and the main Site Coordinator for each study (one per protocol). The Government estimates that a total of 9 FTEs will be required for 'Per Protocol' costs over the four study-active base years of the contract, and 2 FTEs will be required over the 2 option years to complete on-going studies.

This information related to labor estimates is furnished for the Offeror's information only and is not to be considered restrictive for proposal purposes.

SECTION M - EVALUATION FACTORS FOR AWARD

1. **GENERAL**

Selection of an offeror for contract award will be based on an evaluation of proposals against four factors. The factors in order of importance are: technical, cost, past performance and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, past performance, cost/price and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost. The Government intends to make an award(s) to that offeror whose proposal provides the best overall value to the Government.

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed factors listed below.

2. **COST/PRICE EVALUATION**

Offeror(s) cost/price proposal will be evaluated for reasonableness. For a price to be reasonable, it must represent a price to the government that a prudent person would pay when consideration is given to prices in the market. Normally, price reasonableness is established through adequate price competition, but may also be determined through cost and price analysis techniques as described in FAR 15.404.

Cost Realism: The specific elements of each offeror(s) proposed costs are realistic when the proposed cost elements are evaluated and found to: 1) be realistic for the work to be performed; 2) reflect a clear understanding of the requirements; and 3) be consistent with the unique methods of performance and materials described in the offeror(s) technical proposal.

Realism will be evaluated only on the offeror(s) inputs which the Government will use to determine the most probable cost to perform the contract in a manner consistent with the offeror's proposal. Cost realism analysis will be conducted in accordance with FAR 15.404-1(d). The result of the cost realism analysis will be considered in the making the best value tradeoff decision.

3. **HUMAN SUBJECT EVALUATION**

This research project involves human subjects. NIH Policy requires:

a. **Protection of Human Subjects from Research Risks**

The offeror's proposal must address the involvement of human subjects and protections from research risk relating to their participation, or provide sufficient information on the research subjects to allow a determination by NCI that a designated exemption is appropriate.

If you claim that this research should be considered exempt from coverage by the Federal Regulations at 45 CFR 46, the proposal should address why you believe it is exempt, and under which exemption it applies.

The reviewers will evaluate the proposal with regard to four issues: Risks to Human Subjects, Adequacy of Protection Against Risks, Potential Benefits of the Proposed Research to the Subjects and Others, and Importance of the Knowledge to be Gained. See Section L for a complete discussion of what is required to be addressed for each of these issues. Based on the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., concerns are identified as to the protections described against risk to human subjects or no discussion is found regarding protections against risk to human subjects) or "acceptable." If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be

afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for the protection of human subjects from research risks is still found to be unacceptable, then your proposal may not be considered further for award.

b. **Women and Minorities**

Women and members of minority groups and their subpopulations must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. In addition, for NIH-Defined Phase III clinical trials, all proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm , Definitions - Significant Difference) by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable, unless the Government has specified that this solicitation involves a sex/gender specific study or a single or limited number of minority population groups. The proposal also must include one of the following plans:

- Plans to conduct valid analysis to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups,

  OR

- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups (representation of sex/gender and/or racial/ethnic groups as subject selection criterion is not required; however, inclusion and analyses are encouraged),

  OR

- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

Also, the proposal must address the proposed outreach programs for recruiting women and minorities as participants.

Reviewers will consider the areas covered here and in Section L of the solicitation in narrative form in their evaluation. Some of the issues they will evaluate include:

- whether the plan proposed includes minorities and both genders in adequate representation
- how the offeror addresses the inclusion of women and members of minority groups and their subpopulations in the development of a proposal that is appropriate to the scientific objectives of the solicitation
- the description of the proposed study populations in terms of sex/gender and racial/ethnic groups and the rationale for selection of such subjects
- if exclusion is proposed, that the rationale is appropriate with respect to the health of the subjects and/or to the purpose of the research.
- In addition, for gender exclusion, the reviewers will examine the rationale to determine if it is because:

- the purpose of the research constrains the offeror's selection of study participants by gender (e.g., uniquely valuable stored specimens or existing datasets are single gender; very small numbers of subjects are involved; or
- overriding factors dictate selection of subjects); or
- gender representation of specimens or existing datasets cannot be accurately determined, and this does not compromise the scientific objectives of the research.

- For minority group exclusion, the reviewers will examine the rationale to determine if those minority groups are excluded because:
  - inclusion of those groups would be inappropriate with respect to their health; or
  - inclusion of those groups would be inappropriate with respect to the purpose of the research.
- For NIH-defined Phase III clinical trials, reviewers will also consider whether there is an adequate description of plans to conduct analyses to detect significant differences of clinical or public health importance in intervention effect(s) by sex/gender and/or racial ethnic subgroups when the intervention effect(s) is expected in the primary analyses, or if there is an adequate description of plans to conduct valid analyses of the intervention effect in subgroups when the intervention effect(s) is not expected in the primary analyses.

If you determine that inclusion of women and minority populations is not feasible, you must submit a detailed rationale and justification for exclusion of one or both groups from the study population with the technical proposal. The Government will review the rationale to determine if it is appropriate with respect to the health of the subjects and/or the purpose of the research

Based on the evaluation of the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., no discussion can be found regarding the proposed gender/minority inclusion plans, or concerns are identified as to the gender or minority representation, or the proposal does not adequately address limited representation of one gender or minority; or the plan is not in accordance with NIH policy guidelines) or "acceptable." See Section L of the solicitation for the requirements of women/minorities inclusion. If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for the inclusion/ exclusion of women and minorities is still found to be unacceptable, then your proposal may not be considered further for award.

c. **Children**

Children (i.e. individuals under the age of 21) must be included in all human subject research unless there are clear and compelling reasons not to include them.

Your proposal must include a description of plans for including children. If you plan to exclude children from the required research, your proposal must present an acceptable justification for the exclusion. If you determine that exclusion of a specific age range of child is appropriate, your proposal must also address the rationale for such exclusion. Also, the plan must include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation. Also, see Section L of the solicitation for further specific requirements on inclusion of children.

Based on the reviewers' evaluation of the offeror's response, this section of the proposal may be rated "unacceptable" (i.e., no discussion can be found regarding the proposed inclusion plans for children; or concerns are identified as to the offeror's response regarding the inclusion of children; or the plan is not in accordance wit h NIH policy guidelines) or "acceptable." If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for the inclusion of children is still found to be unacceptable, then your proposal may not be considered further for award.

d. **Data and Safety Monitoring**

The offeror's proposal must include a general description of the Data and Safety Monitoring Plan for all clinical trials. The principles of data and safety monitoring require that all biomedical and behavioral clinical trails be monitored to ensure the safe and effective conduct of human subjects research, and to recommend conclusion of the trial when significant benefits or risks are identified or if it is unlikely that the trial can be concluded successfully. Risks associated with participation in research must be minimized to the extent practical and the method and degree of monitoring should be commensurate with risk. Additionally, all plans must include procedures for adverse event reporting. Finally, generally, for Phase III clinical trials, the establishment of a Data and Safety Monitoring Board (DSMB) is required, whereas for Phase I and II clinical trials, the establishment of a DSMB is optional. The reviewers will rely on the Statement of Work and Section L in the solicitation, as well as any further technical evaluation factors in this Section M, as applicable, for the solicitation's specific requirements for data and safety monitoring.

As a part of the evaluation for proposals, the reviewers will consider the acceptability of the proposed data and safety monitoring plan with respect to the potential risks to human participants, complexity of study design, and methods for data analysis. Based on the evaluation of the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., concerns are identified as to the adequacy of the monitoring plan or no discussion can be found regarding the proposed monitoring plans) or "acceptable." If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for data and safety monitoring is still found to be unacceptable, then your proposal may not be considered further for award.

4. **EVALUATION OF OPTIONS**

It is anticipated that any contract(s) awarded from this solicitation will contain option provision(s) and period(s).

In accordance with FAR Clause 52.217-5, Evaluation of Options, (July 1990), the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement, except when it is determined in accordance with FAR 17.206(b) not to be in the Government's best interests. Evaluation of options will not obligate the Government to exercise the option(s).

5. **EVALUATION OF DATA SHARING PLAN**

The offeror's plan for the sharing of final research data shall be assessed for appropriateness and adequacy.

If your proposal does not include a plan or if the plan in your proposal is considered "unacceptable," and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify your data sharing plan during discussions and in your Final Proposal Revision (FPR). If your data sharing plan is still considered "unacceptable" by the Government after discussions, your proposal may not be considered further for award.

6. **TECHNICAL EVALUATION FACTORS**

The evaluation factors are used by the technical evaluation committee when reviewing the technical proposals. The factors below are listed in the order of relative importance with weights assigned for evaluation purposes. Subfactors are listed in order of relative importance.

A. **Technical Approach and Capability - 35%**

Demonstrated understanding of the project requirements and demonstrated understanding of early clinical trial performance as outlined in the Statement of Work. Demonstrated adequacy of the Offeror's approach to each area of the Statement of Work, which includes the approach to the particular tasks and methods of quality control for each task; approach to study design for subject population selection; recruitment and retention plans; target organ and endpoint selection; and statistical evaluation. Demonstrated adequacy of planning for problems in study conduct and completion. Adequacy of two sample Letters of Intent (LOIs) to demonstrate Offeror's approach, target selection, study design, and capability to plan new studies. For proposals involving multiple institutions, demonstrated ability to comply with the DCP Muticenter Guidelines. Demonstrated appropriate monitoring of clinical sites and plans to achieve any needed remedial action. Demonstrated suitable data management processes including collection, quality control and plans for submission to DCP.

B. Qualifications and Availability of Appropriate Personnel and Organizational Experience in Related Areas - 30%

Demonstrated experience and training of the Principal Investigator in leading a team in early drug development and clinical investigations, including but not limited to: design, conduct and analysis of early phase clinical trials with translational biomarker analyses; the management and oversight of clinical trials and clinical studies, including multi-site trials and studies; adherence to Federal regulations and Good Clinical Practice guidelines; protocol-specific requirements for the conduct of research involving human subjects; the development and implementation of standard operating procedures and plans for quality assurance/quality control; the identification of performance problems and deficiencies; and the implementation of remedial actions to address performance problems and deficiencies.

Demonstrated adequacy of training, experience, qualifications, and accomplishments to carry out contract requirements, and availability of the proposed team. Appropriateness of the relative mix of expertise in the following areas: cancer prevention research, clinical trials expertise, data management and quality control, statistical analysis, correlative laboratory studies, and availability of investigational imaging personnel resources. Demonstrated evidence of ability to function as a team for productivity in completion of clinical trials and relevant correlative studies, pathology, imaging, quality control, data management, and adequacy of the ability to receive and transmit documents electronically. Demonstration of pertinent organizational experience in related efforts.

C. Ability to conduct chemoprevention clinical trials - 25%

Appropriateness of the available patient populations and ability to maintain an appropriate rate of accrual and retention across the duration of the trials. Demonstrated ability to identify potential recruitment and retention problems and adequacy of proposed approaches to overcome or minimize anticipated problems and difficulties. Demonstrated mechanisms for prioritization of contract clinical trials/studies with competing studies at the institution(s). Demonstrated ability to coordinate communication and resources, collect and submit data accurately, and to complete trials in a timely manner.

D. Facilities and equipment for cancer and premalignant lesion diagnosis and treatment, participant evaluation, and performance of correlative biomarker studies - 10%

Demonstrated availability, adequacy and suitability of the clinical research facilities, equipment and other resources of the Offeror and all proposed subcontractors (Participating Organizations - POs) for the conduct of clinical trials, biomarker analyses, and other evaluations and analyses in accordance with Federal regulatory requirements and guidelines, including Good Clinical Practice, NIH, NCI and DCP policies and procedures, and the scope and requirements of the RFP. This includes: outpatient and inpatient clinical research facilities; clinical laboratory and clinical research laboratory facilities; research pharmacy facilities; and general clinical research facilities.

7. **EVALUATION OF ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY - SECTION 508**

The offeror's proposal must demonstrate compliance with the "Electronic and Information Technology Accessibility Provisions" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194 for all electronic and information technology (EIT) products and services developed, acquired, maintained, or used under this contract/order, including EIT deliverables such as electronic documents and reports.

If your proposal does not include a completed HHS "Section 508 Product Assessment Template" (hereafter referred to as the "Template") which demonstrates that EIT products and services proposed support applicable Section 508 accessibility standards, or, if the completed "Template" included in your proposal is considered "noncompliant," and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify the "Template" during discussions and in your Final Proposal Revision (FPR). If your "Template" is still considered "noncompliant" by the Government after discussions, your proposal may not be considered further for award.

8. **PAST PERFORMANCE FACTOR**

Offerors' past performance information will be evaluated subsequent to the technical evaluation. However, this evaluation will not be conducted on any offeror whose proposal is determined to be technically unacceptable.

The evaluation will be based on information obtained from references provided by the offeror, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the offeror concerning problems encountered on the identified contracts and corrective action taken.

The government will assess the relative risks associated with each offeror. Performance risks are those associated with an offeror's likelihood of success in performing the acquisition requirements as indicated by that offeror's record of past performance.

The assessment of performance risk is not intended to be a product of a mechanical or mathematical analysis of an offeror's performance on a list of contracts but rather the product of subjective judgment by the Government after it considers relevant information.

When assessing performance risks, the Government will focus on the past performance of the offeror as it relates to all acquisition requirements, such as the offeror's record of performing according to specifications, including standards of good workmanship; the offeror's record of controlling and forecasting costs; the offeror's adherence to contract schedules, including the administrative aspects of performance; the offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the offeror's business-like concern for the interest of the customer.

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the offeror's performance.

The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the offeror.

9. **EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION**

SDB participation will not be scored, but the Government's conclusions about overall commitment and realism of the offeror's SDB Participation targets will be used in determining the relative merits of the offeror's proposal and in selecting the offeror whose proposal is considered to offer the best value to the Government.

The extent of the offeror's Small Disadvantaged Business Participation Targets will be evaluated before determination of the competitive range. Evaluation of SDB participation will be assessed based on consideration of the information presented in the offeror's proposal. The Government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform.

Offers will be evaluated on the following sub-factors:

a. Extent to which SDB concerns are specifically identified

b. Extent of commitment to use SDB concerns

c. Realism of the proposal